ERIC T. SCHNEIDERMAN
Attorney General of the State of New York
By: Christopher Y. Miller
Diana Elkind
Special Assistant Attorneys General
120 Broadway, 12th Floor
New York, New York 10271
Phone: (212) 417-5390/4171
Fax: (212) 417-4604

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* DAVID KESTER, Plaintiffs and Relator, -against - NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	Case No. 11-CIV-8196 (CM) **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT IN INTERVENTION OF THE STATES OF GEORGIA, ILLINOIS, INDIANA, MARYLAND, MICHIGAN, NEW JERSEY, NEW YORK, OKLAHOMA, AND WISCONSIN AGAINST NOVARTIS PHARMACEUTICALS CORPORATION

This is a civil action brought by the states of Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin (the "Intervening States") against Novartis Pharmaceuticals Corporation ("Novartis") to recover treble damages and civil penalties

under their respective False Claims Acts, other state statutes, and the common law. In sum, Novartis orchestrated a kickback scheme to promote one of its prescription drugs that resulted in the submission of false and fraudulent claims to the Medicaid programs of the Intervening States.

I. Nature of the Action

1. Starting in February 2007, Novartis paid kickbacks to a specialty pharmacy, BioScrip, Inc. and its affiliates ("BioScrip"), in connection with Novartis' promotion of its iron-reduction drug, Exjade. These incentives were designed to induce BioScrip to set aside its independent clinical judgment and, instead, carry out marketing activities for Novartis directly with Exjade patients.

2. In order to achieve its sales goals for Exjade, Novartis knew it had to increase the refill rate and, thus, "maximize the life time value of each [Exjade] patient" for the company. Starting in early 2007, Novartis was particularly focused on this objective because its market research had shown that a significant percentage of physicians and patients were opting to discontinue Exjade therapy due to the drug's frequent side effects. To increase the refill rate and thus maximize its Exjade sales, Novartis used a bundle of kickbacks – in the form of patient referrals directed to BioScrip (as detailed below, Novartis dictated the number of new patients referred to BioScrip to fill their Exjade orders) and rebates Novartis paid to BioScrip – to induce BioScrip to initiate and continue a program, from February 2007 to May 2012, that was designed to get Exjade patients to order more refills.

3. Specifically, in February 2007, Novartis leveraged its control over BioScrip's access to Exjade patient referrals to induce BioScrip to initiate an intensive effort to call Exjade patients to recommend refills and to get patients who stopped ordering Exjade to "restart." Then, starting in late 2007, Novartis's Exjade marketing team implemented a system – called "Paying for Performance" – that tied the volume of patient referrals from Novartis and the kickback

payments Novartis paid to BioScrip in the guise of rebates to the pharmacy's delivering higher refill rates and more Exjade shipments for Novartis. In exchange for more patient referrals and higher "rebates" from Novartis, BioScrip assigned employees to call Exjade patients and – under the guise of offering "clinical counseling" or "education" – encourage them to order more refills.

4. Novartis and BioScrip promoted this effort as a nurse-led program that focused on patients and resulted in better clinical outcomes. In fact, however, Novartis and BioScrip understood that BioScrip's program of calling Exjade patients regarding refills was not designed for the patients' benefit. Instead, as Novartis records show, the objective of the program was to increase sales by obtaining more refill orders and, thus, enable Novartis to achieve its "National Exjade Sales Target ($)." As a former BioScrip supervisor has explained under oath, Novartis's system of "tying rebates and patient referrals to the number of refill shipments caused [BioScrip] to be focused exclusively on the number of orders and refill rates, rather than on patient care."

5. Further, as Novartis and BioScrip were aware, the calls from BioScrip did not provide Exjade patients with unbiased clinical information; instead, and unbeknownst to the patients, those calls emphasized the benefits of getting refills and downplayed the significance of Exjade's side effects. For example, from 2007 to late 2010, BioScrip employees were directed to follow a set of talking points for discussing Exjade with patients. Those talking points – which Novartis had reviewed and approved – indicated that "Exjade therapy can cause some discomfort initially, but it usually resolves over time." But those talking points did not disclose the fact that, as the FDA-approved package insert indicated, Exjade treatment had been linked to a lengthy list of severe side effects, including "acute renal failure [that was] fatal in some patients and requiring dialysis in others," "fatal GI hemorrhages," and "non-fatal upper GI irritation, ulceration and hemorrhage."

6. Similarly, Novartis and BioScrip were aware that nearly all the BioScrip employees assigned to "counsel" Exjade patients lacked the clinical knowledge or patient information to provide appropriate counseling to patients regarding Exjade. For example, as former BioScrip employees have acknowledged, they were directed to tell Exjade patients who were experiencing side effects to keep on ordering refills and "manage" the side effects, even though they did not have formal training on Exjade's side effects or how to manage such side effects. Further, even when BioScrip sought information from Novartis in late 2009 regarding whether Exjade was still appropriate for patients with myelodysplastic syndrome ("MDS"), a key group of Exjade patients, Novartis failed to alert BioScrip that Novartis itself had proposed a contra-indication for Exjade for a large segment of MDS patients, *i.e.*, "high-risk" MDS patients.

7. The Exjade kickback scheme, in short, enabled Novartis to have BioScrip perform marketing tasks to increase Exjade sales behind the façade of patient-oriented clinical activities run by an independent healthcare provider. This scheme was highly profitable for Novartis. For example, according to an October 2007 study prepared for Novartis marketing executives, in comparison to the other pharmacies dispensing Exjade, BioScrip generated a $2,000 "net benefit" for Novartis on a per-patient basis. Similarly, when Novartis marketing executives performed a return-on-investment ("ROI") analysis in 2011 to assess the effectiveness of the rebates paid to BioScrip, they determined that Novartis was realizing a 7.8:1 ROI from BioScrip. In other words, for each dollar in kickback paid to BioScrip under the guise of rebates, Novartis obtained $7.80 in return in terms of additional Exjade sales. Indeed, during the course of this kickback scheme, Novartis obtained hundreds of millions of dollars in Exjade sales through BioScrip, including, as relevant here, tens and tens of millions of dollars in sales that were paid for by the Medicaid programs of the Intervening States.

II. Jurisdiction And Venue

8. On November 11, 2011 David Kester (the "Relator") filed a complaint on behalf of himself, the United States, and several states alleging violations of the federal and state False Claims Acts against Novartis and several other defendants. On April 18, 2013 Relator filed an amended complaint on behalf of himself, the United States, and several states alleging violations of the federal and state False Claims Acts against Novartis and several other defendants.

9. On October 30, 2013 the Intervening States filed a notice of partial intervention pursuant to their respective False Claims Acts. On December 16, 2013, the Court entered an Order granting the Intervening States until January 6, 2014 to file their Complaint in Intervention.

10. This Court has subject matter jurisdiction to entertain the original action filed by Relator under 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action arises from the same transaction or occurrence as an action brought under 31 U.S.C. § 3730, and it has supplemental jurisdiction to entertain the state statutory, common, and equitable causes of action pursuant to 28 U.S.C. § 1367(a).

11. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S. C. §§ 1391(b) and 139l(c), because Novartis does business in this district and some of the false or fraudulent acts occurred in this District.

III. Parties

12. Plaintiff the State of Georgia was and is at all relevant times to this action a sovereign state of the United States of America.

13. Plaintiff the State of Illinois was and is at all relevant times to this action a sovereign state of the United States of America.

14. Plaintiff the State of Indiana was and is at all relevant times to this action a sovereign state of the United States of America.

15. Plaintiff the State of Maryland was and is at all relevant times to this action a sovereign state of the United States of America.

16. Plaintiff the State of Michigan was and is at all relevant times to this action a sovereign state of the United States of America.

17. Plaintiff the State of New Jersey was and is at all relevant times to this action a sovereign state of the United States of America.

18. Plaintiff the State of New York was and is at all relevant times to this action a sovereign state of the United States of America.

19. Plaintiff the State of Oklahoma was and is at all relevant times to this action a sovereign state of the United States of America.

20. Plaintiff the State of Wisconsin was and is at all relevant times to this action a sovereign state of the United States of America.

21. Relator is a resident of North Carolina.

22. Defendant Novartis is a subsidiary of Novartis AG, an international pharmaceutical company headquartered in Basel, Switzerland. Defendant Novartis, which is headquartered in East Hanover, New Jersey, does business throughout the United States, including in the Southern District of New York.

IV. The Law

A. The Federal Anti-Kickback Statute And State Prohibitions On Kickbacks

23. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of goods and services that are medically unnecessary, of

poor quality, or even harmful to a vulnerable patient population. To protect patients and federal healthcare programs, including Medicare and Medicaid, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

24. The AKS makes it illegal for individuals or entities to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) ... to any person to induce such person ... to purchase, ... order, ... or recommend purchasing ... or ordering any good ... or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Payments by a pharmaceutical company to pharmacies to induce them to recommend or purchase the company's drugs violate this statute to the extent that the drugs are reimbursed by a federal health care program. Violation of the AKS is a felony punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

25. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the Federal False Claims Act]."

26. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false

claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

27. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federally funded health care programs, including the Medicaid programs of the Intervening States.

28. As early as 1994, concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert concerning prescription drug practices that violated the AKS. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994). The Special Fraud Alert specifically highlighted relationships between drug manufacturers and pharmacists:

> In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. . . . Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.

Id. The Special Fraud Alert went on to warn about arrangements in which "more than nominal" payments are made to a person "in a position to generate business" that are "[r]elated to the volume of business generated." *Id.* In addition, the Special Fraud Alert specifically warned about providing "benefits to pharmacists … in exchange for performing marketing tasks in the course of pharmacy practice." *Id.*

29. All of the Intervening States have anti-kickback statutes, regulations, or requirements that apply to their Medicaid programs. Compliance with these statutes, regulations, or requirements are conditions of payment under the Medicaid programs of the Intervening States, and the Intervening States will not pay for Medicaid claims tainted by kickbacks. These statutes, regulations, and requirements include: Georgia Medicaid Manual, Part I, Section

106(E); Illinois Vendor Fraud and Kickback statute, 305 ILCS 5/8A-3; False Reporting and Other Fraudulent Activities, Ill. Admin. Code tit. 89 § 140.35; Ind. Code § 12-15-24; Md. Crim. Law Code Ann. § 8-511; N.J.S.A. 30:4D–17(c); Mich. Comp. Laws. § 400.604; New York, 18 N.Y.C.R.R. § 515.2(b), § 518.1(c), Soc. Serv. Law § 366-d, N.Y.S. Medicaid Provider Manual, Information for All Providers – General Policy; Okla. Stat. Title 56 §§ 1002, 1005(A)(6); and Wis. Stat. § 49.49(2).

B. The State False Claims Acts And Other Statutes

30. Each of the Intervening States has a state False Claims Act that is modeled on the federal False Claims Act, 31, U.S.C. §§ 3729-33: Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*; Illinois False Claims Act, 740 ILCS 175/3 *et seq.*; Indiana False Claims and Whistleblower Protection Law, Ind. Code 5-11-5.5-1 *et seq.*; Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611; Michigan Medicaid False Claim Act, MCL 400.600, *et seq.*; New Jersey False Claims Act, N.J.S.A. 2A:32C-1, *et seq.*; New York False Claims Act, State Fin. Law §§ 187-194; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053, *et seq.*; and Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2).

31. The core provisions of New York False Claims Act are typical of these state False Claims Acts. The New York False Claims Act provides that any person who:

> a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> c) conspires to commit a violation of [paragraphs (a) or (b)] of this subdivision;
>
> * * *
>
> shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages,

> including consequential damages, which the state or local government sustains because of the act of that person.

N.Y. State Fin. Law § 189(1).

32. "Knowing and knowingly" means that with respect to information, a person:

> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information.

N.Y. State Fin. Law § 188(3).

33. Under the New York False Claims Act, a "claim":

> (a) means any request or demand, whether under a contract or otherwise, for money or property that:
>
> (i) is presented to an officer, employee or agent of the state or a local government; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state or a local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded; or (B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

N.Y. State Fin. Law § 188(1).

34. The Intervening States also have a variety of statutes that allow them to recover monies their Medicaid program's paid for good or services that were tainted by kickbacks.

V. The Intervening States' Medicaid Programs

A. Federal Participation

35. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is to provide matching federal funds and to ensure that states comply with minimum standards in the administration of the program.

36. The federal Medicaid statute sets the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. § 1396, *et seq.*

37. At all times relevant hereto, the United States provided funds to the Intervening States for their Medicaid programs, which are administered by an agency of each state. The Intervening States or their vendors pay health care providers, including pharmacies and physicians, according to established rates, and the federal government then pays a statutorily established share of "the total amount expended . . . as medical assistance under the State plan." *See* 42 U.S.C. §§ 1396b (a)(l). All of the states, including the Intervening States, provide a portion of the funds used to pay claims under their Medicaid programs.

B. Selected Medicaid Regulations And Requirements

38. In each of the Intervening States, health care providers must enroll in each state's Medicaid program in order to be paid for providing goods or services to Medicaid recipients. Each of the Intervening States requires pharmacies to enroll as providers in order to be able to submit prescription drug claims for payment.

39. As part of their Medicaid provider enrollment process, each of the Intervening States requires providers to certify or agree that they will comply with state and federal laws, such as anti-kickback laws, that relate to the provision of goods and services under the Medicaid program. In addition, some of the Intervening States require providers to subsequently certify that they will comply with state and federal laws, such as anti-kickback laws, relating to the provision of goods and services under the Medicaid program. For example, the New York Medicaid program requires providers like pharmacies to certify that "I (or the entity have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations." This annual "Certification

Statement for Provider Billing Medicaid" further provides that "all claims are made in full compliance with the pertinent provisions of the [Medicaid] Manual," which prohibits kickbacks, and that the information provided is "true, accurate and complete" and that "no material fact has been omitted." The other eight Intervening States have similar statutory, regulatory, and program requirements, which were also in effect prior to March 2010. They are set forth below:

40. *Georgia*: Section 106(B) of Georgia's Medicaid Manual requires Providers, including pharmacies such as BioScrip, to "[c]omply with all State and Federal laws and regulations related to furnishing Medicaid/PeachCare for Kids services." Section 106(E) of Georgia's Medicaid Manual also prohibits any "offer or payment of remuneration, whether direct, indirect, overt, covert, in cash or in kind, in return for the referral of a Medicaid [beneficiary]." In addition, Section 106(J) of the Part I Medicaid Manual prohibits Providers from "bill[ing] the Division for any services not performed or delivered in accordance with all applicable policies" and from "submit[ting] false or inaccurate information to the Division relating to … claims… for services rendered." Section 405(E) of the Part I Medicaid Manual authorizes Georgia to deny reimbursement for "[n]oncompliance with any of the Division's applicable policies and procedures," and Section 407(F) of the Part I Medicaid Manual permits Georgia to recoup reimbursement when a provider fails to "comply with all terms and conditions of participation related to the service(s) for which a claim has been paid."

41. To be eligible for payments from Georgia's Medicaid program, Providers, including pharmacies such as BioScrip, must execute a Statement of Participation. The Statement of Participation entered into by BioScrip in 1997 "establishe[d] the means and terms of reimbursement between [Georgia Medicaid] and the [Provider]." The Statement of Participation unequivocally states that Georgia Medicaid will only "reimburse for such claims, and in such amounts, as meet the provisions of … applicable federal and state laws, [HHS]

regulations, … and the applicable terms and conditions for receipt of Medical Assistance published in [Georgia's] Policies and Procedures Manuals and amendments thereto."

42. Further, in its Statement of Participation, BioScrip, "in consideration of the right to submit payment claims by electronic media billing", "agree[d]", "certif[ied]", and "stipulate[d]" that it would "abide by" certain terms and conditions. These terms and conditions include: "[t]hat Provider and every person or agent acting on his behalf shall abide by all Federal and State statutes, rules and regulations governing the Georgia Medicaid Program"; "[t]hat all Electronic Media Billing claims submissions by Provider shall be true, accurate, and complete, and Provider's signature on this agreement shall be binding as certification of such…"; and "[t]hat payment of claims submitted by Provider, or its billing agent, will be from Federal and State funds and that any false claim or statement or concealment or failure to disclose a material fact may be prosecuted under applicable Federal and/or State Law and fined or imprisoned as provided by law."

43. *Illinois*: To be eligible for payment in the Illinois Medicaid program, providers—including pharmacies—are required to submit a provider agreement in which the provider "agrees, on a continuing basis, to comply with Federal standards specified in Title XIX and XXI of the Social Security Act and with all other applicable Federal and State laws []." The provider must "acknowledge[] that it understands the laws and handbook provisions regarding services and certifies that the services will be provided in compliance with such laws and handbook provisions" and "further acknowledges that compliance with such laws and handbook provisions is a condition of payment for all claims submitted."

44. In addition to expressly conditioning payment on AKS compliance through its provider agreement, the Illinois Handbook for Providers of Medical Services specifies: "Providers are subject to State and federal laws pertaining to penalties for vendor fraud and

kickbacks." Illinois Handbook for Providers of Medical Services, Chap. 100, § 136. The handbook also specifies that the State "actively monitors all claims for payments" to identify possible fraud, which includes claims that were for services not rendered in accordance with "civil and criminal" laws applicable to Medicaid. *See id.*

45. *Indiana*: In Indiana, a Medicaid provider who solicits, offers, or receives a kickback in connection with the furnishing of goods or services to a Medicaid recipient commits a misdemeanor. Ind. Code § 12-15-24-2. For the purposes of Indiana's theft statute, Ind. Code § 35-43-4-2, evidence that a Medicaid provider received a kickback is prima facie evidence that the provider intended to deprive the state of a part of the value of the payment received from the state, one of the elements of theft, a felony. Ind. Code § 12-15-24-1. A provider who receives a kickback in connection with the furnishing of goods or services to a Medicaid recipient and who files a Medicaid claim for the furnishing of those goods or services commits Medicaid Fraud, a felony. Ind. Code § 35-43-5-7.1.

46. Indiana Medicaid will only pay reimbursements for pharmacy services when the services are provided in accordance with all applicable laws, rules of the Indiana Medicaid program, and the Medicaid provider manual and not specifically excluded from coverage by the Indiana Medicaid program rules. 405 Ind. Admin. Code § 5-24-1. Payment may be denied if the claim is a false or fraudulent claim, is in violation of state or federal Medicaid laws or rules, or is a claim for which federal financial participation is not available (e.g., a claim in violation of the federal AKS). 405 Ind. Admin. Code § 1-1-4.

47. *Maryland*: Maryland's anti-kickback law, codified as part of the state's Medicaid Fraud statutes, makes it a felony to "solicit, offer, make, or receive a kickback or bribe in connection with providing" goods or services valued at $1,000 or more in the aggregate under Medicaid. Md. Crim. L. §§ 8-511; 8-516 (c).

48. To receive reimbursements from Maryland Medicaid, pharmacies are required to have in effect a provider agreement with the state's Medicaid agency. *See* Code of Md. Reg. § 10.09.36.03 (A)(5). The Maryland Medicaid provider agreement, in turn, requires the pharmacy to agree "to comply with all of the applicable requirements of the Maryland Medical Assistance Program" and to "acknowledge[]" its "responsibility to become familiar with those requirements."

49. In addition to conditioning Medicaid payments on AKS compliance through the provider agreement, Maryland's Medicaid regulations also expressly authorize the "[w]ithholding of payment" if it had been determined "that a provider [or] pharmacist … has failed to comply with applicable federal or State laws or regulations," such as the AKS and Maryland's version of the AKS. Code of Md. Reg. § 10.09.03.09 (A) (2).

50. *Michigan*: To be eligible for payments from Michigan's Medicaid program, pharmacies are required to execute a pharmacy provider enrollment and trading partner agreement and to certify that, "by signing this agreement," they "agree[d] to the [agreement's] conditions and provisions." Specifically, one of the conditions in that agreement is that pharmacies "agree[d] to comply with the provisions of … Act No. 280 of the Public Acts of 1939, as amended," which includes Michigan's Medicaid anti-kickback statute.

51. Michigan's anti-kickback statute, MI. Stat. § 400.604, makes it a felony to "solicit[], offer[], or receive[] a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part" by Michigan's Medicaid program. *Id.*

52. In addition to requiring pharmacies to certify that they would not engage in kickback arrangements through the provider enrollment and trading partner agreement, Michigan's Medicaid program manuals also indicate that reimbursements are conditioned on

compliance with applicable federal and state laws, including the federal AKS and Michigan's anti-kickback statute. For example, section 3.1 of the Michigan Medicaid's pharmacy manual provides that "applicable State and Federal laws … must be observed by participating pharmacies." Section 16.2 of the Michigan Medicaid program manual also expressly states that "receiving kickbacks" is an example of prohibited "Medicaid fraud."

53. *New Jersey*: The New Jersey law, regulations and provider agreements governing its Medicaid Program set forth a comprehensive scheme to prohibit kickbacks and to condition payment of Medicaid funds on compliance with applicable federal and state laws, including the respective federal and state Anti-Kickback Statutes.

54. The New Jersey AKS makes it a crime for any "provider, or any person, firm, partnership, corporation, or entity" to solicit, offer or receive any "kickback, rebate, or bribe in connection with" Medicaid claims. N.J.S.A. 30:4D-17 (c). In addition, the New Jersey Department of Human Services, Division of Medical Assistance and Health Services (New Jersey's Single State Agency) regulations condition reimbursement on providers' compliance with applicable federal and state laws, including the federal AKS and New Jersey's AKS. Specifically, the Single State Agency has the authority to withhold payment for "[c]laims for services, goods or supplies which are furnished, rendered, prescribed or ordered in violation of Federal or State civil or criminal statutes…." N.J.A.C. 10:49-5.5 (a)(17). Moreover, the Single State Agency has the authority to exclude a party from the Medicaid Program for violating the "anti kickback provisions" of federal law (N.J.A.C. 10:49-11.1 (d)(3)) or violating "any provision of N.J.S.A. 30:4D-1 *et seq.*" (which includes the New Jersey AKS). N.J.A.C. 10:49-11.1 (d)(20).

55. In addition to the laws and regulations that prohibit kickbacks, to participate in the Medicaid Program, providers, including pharmacies, are required to execute a provider

agreement. That agreement puts providers on notice that "[t]here are Federal and State Statutes and Regulations governing kickbacks and referral practices which may apply to you … [including], but are not limited to: the Federal Medicare and Medicaid Anti-Kickback Statute (42 USC 1320A-7b(b)) … the State Medicaid Anti Kickback Statute (N.J.S.A. 30:4D-17(c))…." The provider agreement further directs providers to "carefully review and understand these legal requirements and prohibitions" because, by "signing [this] agreement," providers give their "representation that there is compliance with all these requirements."

56. *Oklahoma*: Oklahoma, through regulatory authority and Oklahoma Medicaid Provider Agreements, requires providers such as Bioscrip to certify compliance with federal and state law. The Oklahoma Administrative Code states, "[i]n order to be eligible for payment, providers must have on file … an approved Provider Agreement," with the state's Medicaid agency and "[t]hrough this agreement, the provider certifies all information submitted on claims is accurate and complete, assures that the State Agency's requirements are met and assures compliance with all applicable Federal and State regulations." Okla. Admin. Code § 317:30-3-2. Furthermore, kickbacks are prohibited in Oklahoma by way of the Federal AKS, as well as the Oklahoma Medicaid Program Integrity Act, which provides in relevant part, that it is unlawful to "willfully and knowingly . . . [s]olicit or accept a … kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program." 56 Okl. St. Ann. § 1005 (A)(6). Therefore, if a kickback is solicited or accepted, a related claim is ineligible for payment by the Oklahoma Medicaid Program.

57. Through the provider agreements, providers, such as Bioscrip, certify that they would "comply with all applicable Medicaid statutes, regulations, policies, and properly promulgated rules" of the Oklahoma Medicaid agency. Providers also acknowledge that "all claims [would] be satisfied from federal and state funds" and any "false claims, statements, or

documents, or any concealment of a material fact may be prosecuted" under applicable federal or state laws."

58. In addition, Chapter 2 of Oklahoma Medicaid's Provider Billing and Procedure Manual states that the providers are not entitled to payments for "services not covered under the scope of" Oklahoma's Medicaid Program, which includes services connected to kickback arrangements. Indeed, the Manual further specifies that "claims [for such non-covered services] will be denied or payment will be recouped…."

59. *Wisconsin*: Wisconsin's anti-kickback law, codified as part of Wisconsin's Medicaid fraud statute, classifies as a felony the offer, payment, solicitation, or receipt of any remuneration "including any kickback, bribe, or rebate directly or indirectly, overtly or covertly, in cash or in kind" for the "furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a medical assistance program…" *See* Wis. Stat. § 49.49 (2) (re-codified in 2013 as Wis. Stat. § 946.91 (3)).

60. In Wisconsin, a "provider" is one who has been "certified by the department to provide health care services to recipients and to be reimbursed by MA for those services." Wis. Admin. Code § DHS 101.03 (137). Providers are required to comply with the condition of being certified. Wis. Admin. Code §§ DHS 106.01, 106.02 (1). In order to be certified by the department, a provider must "[e]xecute a provider agreement with the department." Wis. Admin. Code § DHS 105.01 (3)(e). Pursuant to that agreement, the provider "acknowledges that certain terms, conditions, and restrictions that are either listed [in the provider agreement], set forth in applicable law, or available to the Provider through Wisconsin Medicaid govern its participation as a provider in Wisconsin Medicaid, and that by submitting claims as a Wisconsin Medicaid provider, the Provider becomes subject to those terms, conditions, and restrictions." In addition, the "Provider further acknowledges that all applicable terms, conditions, and restrictions govern

the Provider's participation in Wisconsin Medicaid, regardless whether the Provider has actual knowledge of those terms, conditions, and restrictions."

61. Furthermore, by regulation, Wisconsin Medicaid has expressly linked its payment for claims on the underlying services being in compliance with applicable federal and state laws, including the AKS and Wisconsin's anti-kickback statute. *See* Wis. Admin. Code § DHS 107.02 (2)(a). Specifically, that regulation defines "[s]ervices which fail[ed] to comply with…state and federal statutes" as "non-reimbursable services." *Id.*

62. Also, all of the Intervening States require pharmacists to be licensed as pharmacists in their respective states. In all of the Intervening States, pharmacists are considered health care providers who have duties to the patients they serve. These duties include the duty to exercise independent decision-making for the benefit of patients.

C. Reimbursement For Exjade

63. The Medicaid programs in all of the Intervening States pay for certain prescription drug claims submitted by pharmacies that are enrolled in their respective Medicaid programs. The Medicaid programs in each of the Intervening States have paid pharmacies for claims relating to Exjade following its launch in November 2005.

64. BioScrip, Inc. is a Delaware corporation with headquarters in Elmsford, New York. During all relevant times, BioScrip affiliates were enrolled as Medicaid providers in all of the Intervening States. BioScrip sold most of its pharmacy operations to another company in May 2012.

65. From at least February 2007 to May 2012, Novartis paid kickbacks to BioScrip to induce it to purchase Exjade and to recommend that patients refill their Exjade prescriptions or resume taking Exjade. As part of this kickback scheme, BioScrip personnel made tens of thousands of calls to Medicaid recipients in the Intervening States, in addition to over 100,000

automated refill calls from February 2007 to May 2012. During this period, the Medicaid programs of the Intervening States or their vendors paid over $50 million to BioScrip affiliates for Exjade claims. The approximate amounts for each of the Intervening States during this period are as follows: Georgia ($15.1 million); Illinois ($9.2 million); Indiana ($1.1 million); Maryland ($4.9 million); Michigan ($5.5 million); New Jersey ($5.1 million); New York ($15.2 million); Oklahoma ($2.0 million); and Wisconsin ($5.1 million).

66. In order for a pharmacy to be paid for dispensing a prescription drug to a Medicaid recipient, the pharmacy must submit a claim for payment. During the period from February 2007 to May 2012, BioScrip or its affiliates submitted thousands of claims for payment to the Medicaid programs of the Intervening States or one of their vendors relating to Exjade prescriptions. The approximate number of claims for the following Intervening States during this period is as follows: Georgia (4,200); Illinois (2,500); Maryland (2,300); Michigan (1,400); New Jersey (1,500); New York (4,800); Oklahoma (350); and Wisconsin (1,900).

VI. Novartis' Knowledge Of Its Obligations To Comply With The Federal AKS and Similar State Prohibitions

A. Novartis Knew Many Exjade Patients Were Medicaid Recipients

67. At all relevant times, Novartis was well aware that state Medicaid programs paid for a substantial percentage of the Exjade claims submitted by the pharmacies in its exclusive distribution network for the drug, including BioScrip. In late 2005, Novartis asked several pharmacies to submit proposals to become part of this network. At the time, Novartis expected that a substantial number of Exjade patients would be Medicaid recipients. As a result, one of the key criteria that Novartis used in selecting the pharmacies was whether they were Medicaid providers that could ship Exjade to Medicaid recipients across the country. After Exjade was launched, Novartis received data from this network that showed a substantial number of Exjade patients were Medicaid recipients.

B. Novartis' Compliance Policies

68. Novartis knew that it was required to comply with the federal AKS and state anti-kickback laws in promoting Exjade to health care professionals, including pharmacies. First, as a matter of written policy, Novartis recognized that "any member of the ... pharmacy ... profession" is a healthcare professional, and that Novartis should not interfere with the pharmacy's independence by offering anything "intended to have an inappropriate influence on the [pharmacy's] decision to [] dispense, recommend, purchase, supply, or administer products." See Novartis Pharma Principles & Practices for Professionals at 2-4.

69. More specifically, Novartis's Ethics and Compliance Policies ("Novartis E&C Policies"), first issued in 2003 and reissued in 2006, 2008, 2010, and 2011, have required its employees to comply with state and federal anti-kickback laws. The E&C policies have summarized these laws as follows:

> The Federal Anti-kickback Statute makes it illegal to knowingly and willfully provide any "remuneration" in return for:
>
> (1) referring a person to another person for items or services covered under federal health care programs; or
>
> (2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.
>
> "Remuneration" is defined very broadly and includes any item of value which is provided with the intent to induce the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program – not just Medicare and Medicaid ([TRICARE], VA benefits, etc.). Note again that many state statutes similarly prohibit such activities.
>
> Under the Anti-kickback Statute, it is illegal to solicit (ask for) or receive kickbacks, as well as to offer to pay a kickback. Any of these actions constitutes a felony and is punishable by a fine up to $25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity's right to provide products and services to patients whose care is paid for by

government programs.

70. Further, since at least 2008, the E&C Policies have highlighted the fact that the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG") has "identified a number of specific risk areas for pharmaceutical manufacturers" like Novartis. As relevant here, those include:

- "Discounts and other remuneration to purchasers;" and
- "Relationships with physicians and other persons and entities in a position to make or influence referrals (e.g., potential conflicts of interest, prescription switching arrangements, ...)."

71. The Novartis E&C Policies relating to the AKS have also specified that "[j]udicial and administrative interpretations of this law have been very broad" and that "[t]he statute is violated if even one purpose (as opposed to a primary or sole purpose) is to induce the Healthcare Provider to prescribe its product."

72. In addition, the Novartis E&C Policies have recognized that "[t]he fact that a particular arrangement is common in the health care industry is not a defense."

73. Novartis executives responsible for overseeing the promotion of Exjade understood that the AKS applied to Novartis' relationships with pharmacies that dispensed Exjade and that it was part of their job responsibilities to ensure that those relationships complied with the AKS.

C. Novartis' 2010 Civil Settlements, Guilty Plea, and Obligations Under its 2010 Corporate Integrity Agreement

74. In September 2010, and following the filing of several civil actions alleging AKS violations and other healthcare fraud claims, Novartis entered into a settlement with the Government and several states. The civil settlement provided, in relevant parts, that Novartis

violated the AKS by giving "illegal remuneration ... to health care professionals to induce them to promote and prescribe" certain Novartis drugs. Concurrently, Novartis pled guilty to a criminal information, admitting to violating the misbranding provision of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 331(a).

75. In conjunction with the resolution of the criminal and civil cases, Novartis entered into a Corporate Integrity Agreement (the "Novartis CIA") with HHS-OIG in September 2010.

76. The Novartis CIA requires Novartis, among other things, to "ensure that [its] Policies and Procedures address ... appropriate ways to conduct Promotional Functions in compliance 'with all applicable Federal healthcare program requirements, including ... the federal anti-kickback statute ... and the False Claims Act ...." Novartis CIA at§ III(B)(3)(c).

77. In addition, the Novartis CIA mandates that executives in key positions throughout Novartis submit annual certifications to HHS-OIG to attest to their compliance with federal laws, the CIA's requirements, and Novartis policies. Id. at§ III(A)(4).

78. To facilitate prompt detection of unlawful activities, the Novartis CIA requires Novartis to notify HHS-OIG, in writing, of all probable violations of criminal, civil, or administrative laws applicable to any federal health care program, including violations of the AKS. *Id*. at § III(H).

THE EXJADE KICKBACK SCHEME

VII. Exjade's Indicated Use And Safety Profile

79. In November 2005, FDA approved Exjade for use in treating "chronic iron overload due to blood transfusions … in patients 2 years of age and older." Repeated blood transfusions can lead to a build-up of iron in the body; and excess iron can cause damage to organs such as the liver or the pancreas. Exjade, an iron-chelation drug, helps remove iron from a patient's body.

80. Novartis obtained FDA approval for Exjade under an accelerated process established pursuant to 21 C.F.R. § 314.510. Due to Exjade's accelerated approval by the FDA, Novartis was required to conduct several post-approval studies regarding Exjade's efficacy and side effects. In addition, FDA regulations required Novartis to submit all Exjade promotional materials to FDA for review at least 30 days before their use. *See* 21 C.F.R. § 314.550.

81. Patients can receive blood transfusions in connection with a variety of health problems. Thus, Exjade has been prescribed for patients with a number of underlying conditions, the most common conditions being beta-thalassemia (a blood disorder that affects red blood cells), sickle cell disease (a blood disorder that causes red blood cells to assume a sickle shape), and myelodysplastic syndrome (or "MDS," which encompasses a collection of bone marrow disorders that affect the production of the myeleoid type of blood cells).

82. Novartis, in turn, classified the market for Exjade as comprising four types of patients: (1) patients with beta-thalassemia, (2) patients with sickle cell disease, (3) MDS patients, and (4) patients with "other anemias" that required blood transfusions.

83. According to pre-approval clinical studies for Exjade, the most frequent adverse events reported during the pre-approval studies included vomiting, nausea, abdominal pain, and an increase in serum creatinine (a clinical measure of kidney function). Thus, the original, November 2005 Exjade package insert (commonly referred to the "Exjade label") provided warnings about potential effects on the kidneys and liver, and recommended that monthly tests be conducted on the functioning of those organs, along with monthly serum ferritin tests (a clinical measure of a patient's blood iron level).

84. However, after patients began to use Exjade outside of the clinical study setting, Exjade's safety profile worsened significantly in terms of both the frequency and severity of reported adverse reactions. For instance, according to internal Novartis records, Novartis recognized by early 2007 that the adverse events associated with Exjade "are higher in the real world than reported in clinical trials."

85. In addition, post-approval safety studies showed that the adverse reactions associated with Exjade use also were more severe. These findings led to the addition of numerous warnings to the Exjade label, including:

- In late 2006, the Exjade label was updated to indicate that kidney failures and cytopenias (a reduction in production of certain blood cells) had been reported.
- In April 2007, the Exjade label was updated to report that some patients with kidney failure and cytopenias had died.
- In January 2008, a clinical recommendation was added to the Exjade label, emphasizing to prescribers that prescribing Exjade to patients to remove iron should be based on the anticipated "clinical benefit and risks of Exjade

therapy." In addition, the updated Exjade label also included a warning about liver failures.

- In October 2008, two more warnings were added to the Exjade label — one regarding gastrointestinal ulcerations and bleeding, and the other regarding Exjade's toxicity at higher doses for patients with lower blood iron levels.

86. In January 2010, the safety concerns culminated in the requirement that the Exjade label feature a "Black Box" warning.[1] As Novartis records show, the January 2010 label change resulted from an extensive analysis of Exjade safety data mandated by FDA. Specifically, in April 2009, FDA asked Novartis to analyze reports of patients who died while taking Exjade, as well as the risks and benefits of Exjade to MDS patients.

87. Novartis, in turn, submitted two responses to FDA's questions. First, in July 2009, Novartis responded to FDA and recommended that Exjade be contra-indicated for certain MDS patients. Then, in September 2009, Novartis reported that, according to an analysis of the more than 1,800 deaths of Exjade patients reported in an adverse event database, more than 1,000 of these patients were classified as having MDS.

88. Finally, in January 2010, the "Black Box" warning was added to the revised Exjade label, highlighting the fact that "Exjade may cause" kidney failure, liver failure, and gastrointestinal hemorrhage, and that "[i]n some reported cases these reactions were fatal." The revised label also specified that Exjade was contraindicated for patients with "high-risk MDS," *i.e.*, MDS patients who are sicker than other MDS patients. In that regard, internal Novartis

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[1] The "Black Box" warning is the strongest warning for a prescription drug that the FDA can require. Pursuant to FDA regulations, the warning must be in bold print and presented in a format that makes the information visually accessible. *See* 21 C.F.R. §§ 201.57(c)–(d).

records show that Novartis knew that more than 40% of MDS patients using Exjade in late 2009 had high-risk MDS and, thus, were "inappropriate patients" for Exjade.

VIII. Novartis' Distribution And Marketing Strategies For Exjade

A. Within The EPASS Distribution Network It Created, Novartis Controlled The Volume of Exjade Patient Referrals To BioScrip And The Other EPASS Pharmacies

89. Prior to launching the drug, Novartis decided to establish an exclusive distribution system for Exjade that would be responsible for processing and fulfilling close to all of the Exjade prescriptions. This system, which Novartis called the EPASS ("Exjade Patient Assistance and Support Services") network, was designed to include three pharmacies that were responsible for dispensing Exjade, and a data vendor that, among other things, processed incoming Exjade prescriptions and allocated the patients among the three EPASS pharmacies.

90. BioScrip applied to participate in the EPASS network in August 2005, and was selected by Novartis in late 2005 as one of the three EPASS pharmacies. BioScrip and Novartis entered into a contract in November 2005 concerning their relationship and BioScrip's role in the EPASS network (the "2005 BioScrip Exjade Contract").

91. Under that initial contract, BioScrip was principally responsible for sending Exjade shipments to patients, contacting Exjade patients to determine whether they wanted to order refills, and confirming that the shipments had been received. Novartis and BioScrip understood that BioScrip needed to obtain an Exjade patient's consent before shipping a refill even if a doctor's prescription authorized such a refill.

92. The 2005 BioScrip Exjade Contract also provided for BioScrip to assist Novartis with enrolling patients in education programs that Novartis planned to establish, including one

called "Simple Steps."[2] In addition, BioScrip agreed to submit to Novartis, through the EPASS hub, detailed information regarding Exjade patients' course of therapy, including the medical conditions for which the patients were receiving Exjade, the patients' dosage, whether patients ordered refills, and whether physicians discontinued therapy.

93. In return for these services, the 2005 BioScrip Exjade Contract entitled BioScrip to receive a per-shipment rebate of $13 from Novartis. But, as Novartis understood, beyond the rebates, just having access to patient referrals as a member of the EPASS network was very valuable to BioScrip: getting more Exjade patients translated to higher sales, larger Medicare and Medicaid reimbursements, higher dispensing fees, and more rebates from Novartis.

94. Exjade prescriptions (with limited exceptions) had to be issued on an "EPASS enrollment form" and submitted to the EPASS data vendor. Because the great majority of Exjade prescriptions were funneled through EPASS, Novartis had the ability to allocate thousands of new patient referrals among the EPASS pharmacies. More specifically, Novartis had unfettered control over how the EPASS data vendor allocated approximately half of all new patients whose insurers and doctors did not specify a choice of pharmacy (the "undesignated patients"). In this regard, the 2005 BioScrip Exjade Contract did not contain any provision that conditioned BioScrip's access to patient referrals or its participation in EPASS to any performance threshold, such as BioScrip's refill or shipment level.

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[2] As internal Novartis e-mails show, Novartis was unable to obtain FDA approval for a large number of "patient education" materials to be used as part of Simple Steps. Thus, Novartis abandoned the program in mid-2007, before it had been meaningfully implemented.

B. Novartis Focused On Maximizing Refills As A Means To Achieve Its Sales Targets And Profit Objectives For Exjade

95. For Novartis, maximizing the number of refills for each patient was essential to meeting its sales targets and profit objectives for Exjade. This was because, as Novartis recognized, the population of potential Exjade patients, was "very small," comprising only "about 15 out of [every] 100,000 people." Thus, even before the drug was launched, one of the Exjade marketing team's imperatives was to "maximiz[e] the life time value of each patient" to Novartis.

96. By early 2007, increasing the refill rate per patient became even more important for Novartis because fewer than expected Exjade patients were ordering refills. As the Exjade marketing team understood, two of the main causes for the falling refill rate among Exjade patients were (i) the frequency of side effects experienced by Exjade patients, and (ii) changes in the composition of patients starting Exjade therapy.

97. In terms of Exjade's side effects, the Exjade marketing team understood that the side effects were both more frequent and more severe than the pre-approval clinical studies had indicated and, further, were leading a significant percentage of prescribers and patients to decide against ordering refills. For example, according to a marketing study Novartis received in early 2007, only "53% of physicians believe [Exjade's] potential side effects can be effectively managed without discontinuation." Moreover, the data submitted by the EPASS pharmacies also showed the Exjade marketing team that side effects were a major cause for patients to stop ordering Exjade.

98. Further, by early 2007, Novartis also knew that the composition of Exjade patients was shifting to fewer patients who received transfusions on a regular basis and a higher

percentage of "intermittent" patients (*i.e.*, patients who had blood transfusions intermittently) with "lower iron overload" levels.[3] As the head of the Exjade marketing team acknowledged in a February 2007 e-mail, the intermittent patients were more likely to stop getting Exjade refills "after several months" because they would "have almost normalized iron values."

99. For Novartis's Exjade marketing team, the prospect of fewer refills per patient represented a "key issue" to its ability to achieve the Exjade sales target for 2007. Thus, by March 2007, the marketing team identified "improve[ing] refill rates" among Exjade patients and "generat[ing] 're-starts'" (*i.e.*, getting patients who stopped ordering Exjade refills to resume ordering) as one of its top three priorities.

100. Indeed, improving refill rates among Exjade patients, which Novartis called "adherence," was the "top strategic imperative" for the Exjade marketing team in late 2007 and 2008. Further, as Novartis records show, getting Exjade patients to order more refills continued to be a key marketing objective for Novartis from 2009 to 2012.

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[3] As Novartis records show, a significant number of the patients who started using Exjade in late 2005 and 2006 had switched from Desferal, another iron-chelation drug that must be administered through daily injections. This meant that Desferal patients typically had high iron levels and required chronic blood transfusions. By 2007, fewer patients were switching to Exjade from Desferal. Thus, Novartis focused on expanding the patient population for Exjade by targeting patients who had lower blood iron levels and/or required less frequent transfusions.

IX. Starting In February 2007, Novartis Leveraged Its Control Over Patient Referrals To Make BioScrip Recommend Refills Directly To Exjade Patients

101. As noted above, the Exjade marketing team saw the falling refill rate as a "key risk" to its being able to achieve Novartis's Exjade sales target for 2007. Indeed, by early 2007, senior executives at Novartis were concerned about an emerging "performance gap" between the "actual" level of Exjade sales and the "budget[ed]" sales target for Exjade. For example, for the month of January 2007, Novartis only obtained $12.57 million in net sales for Exjade, well short of its budget "goal of $15.6 [million]."

102. By February 2007, the Exjade marketing team was particularly concerned about the refill level at BioScrip, which – while "higher than [Novartis's] original 2006 forecast" – was below the refill levels at the other two EPASS pharmacies. According to a February 2007 Novartis financial analysis, the difference in refill levels translated into millions of dollars in Exjade sales for Novartis.

103. To obtain more refill orders through BioScrip, the Exjade marketing team decided to leverage Novartis's control over patient referrals to make BioScrip recommend refills to Exjade patients. More specifically, in late February 2007, Novartis advised BioScrip that, because it generated lower levels of refills as compared to the other two EPASS pharmacies, BioScrip had been placed under a "performance improvement plan" (the "PIP").

104. As Novartis executives explained to BioScrip at a February 2007 meeting at Novartis's offices in New Hanover, New Jersey, the PIP was a 45-day period – from late February to early April – during which BioScrip had to increase the refill level among its Exjade patients and convince as many of the Exjade patients who had stopped ordering refills to resume ordering. In addition, as part of the PIP, Novartis also made BioScrip provide weekly updates

about the numbers of Exjade refill orders that it obtained and the number of patients that BioScrip was able to "restart" on Exjade.

105. Although neither the 2005 BioScrip Exjade Contract nor any of its amendments required BioScrip to maintain any refill level, Novartis knew that it could impose the PIP on BioScrip because it controlled access to Exjade patient referrals, which were valuable to BioScrip. Specifically, Novartis informed BioScrip that unless it complied with the PIP and achieved certain "success measures," such as raising its refill levels, Novartis would cut off the flow of undesignated patient referrals to BioScrip or remove BioScrip from the EPASS network.

106. In response to the threat of losing access to Exjade patient referrals, BioScrip initiated an intensive effort to obtain more refill orders from its Exjade patients and to convince patients who had stopped ordering Exjade refills to resume ordering. Specifically, a group of employees in BioScrip's specialty pharmacy unit – including a newly-hired licensed practical nurse ("LPN"), two or three medical assistants, and several customer service representatives ("CSRs") – were assigned to call Exjade patients to encourage them to order refills and to call patients who had stopped ordering Exjade refills to encourage them to resume ordering.

107. However, when BioScrip employees recommended Exjade refills to patients during those calls, their recommendations were not based on assessments of whether refills were clinically appropriate. Instead, BioScrip employees were directed to encourage patients to order Exjade refills or resume ordering without regard to whether the patients were experiencing potentially significant side effects or had achieved their therapeutic goals.

108. For example, according to the newly-hired LPN who made calls during this period, she was assigned to call Exjade patients "immediately upon starting work at BioScrip."

She was not "given training on Exjade or its side effects" and "did not know [which] side effects were typical or unusual." Nonetheless, when she reached Exjade patients over the phone, she was directed to "emphasize to patients the importance of staying on Exjade" and "counsel patients to manage any side effects they had."

109. By April 2007, BioScrip's intensive efforts to recommend refills had resulted in a significant increase in the refill level among its Exjade patients, and BioScrip employees had convinced 139 patients to resume ordering Exjade. Further, BioScrip also promised Novartis that it would continue assigning one or more nurses to call Exjade patients "to keep[] these patients on drug therapy." Based on those results and BioScrip's pledge to maintain its focus on recommending Exjade refills to patients, the Exjade marketing team at Novartis decided that BioScrip had passed the PIP and would continue to receive undesignated patient referrals.

110. Nonetheless, Novartis continued to monitor closely BioScrip's efforts in recommending refills to Exjade patients and the level of refill orders at BioScrip. Specifically, starting from July 2007, the Exjade marketing team held monthly teleconference calls (and some in-person meetings) with BioScrip to discuss its refill rates as shown in the monthly "Exjade Scorecard" — a spreadsheet created by Novartis to compare the Exjade refill rates at BioScrip and the other two EPASS pharmacies.

111. To avoid the risk of losing access to Exjade patient referrals, BioScrip continued its efforts to call patients and encourage them to order Exjade refills or restart on Exjade, and, starting in mid-2007, formalized the staffing and procedures for these calls. BioScrip created a team that was supposed to work exclusively on Exjade (the "Exjade Team"), consisting of the LPN hired in early 2007, two or three medical assistants, and several CSRs (for a few months in

mid-2007, BioScrip assigned a second LPN to the Exjade Team; otherwise, there was only one LPN on the Exjade Team from 2007 to 2012). BioScrip also created a protocol, which it named "ScripCare" (also referred to as "BioScripCare" in BioScrip's records) that provided the Exjade Team with a basic timeline for calling Exjade patients to encourage them to order refills and certain scripts for how to discuss Exjade therapy with new patients.

112. Novartis, in turn, advised BioScrip on the creation of ScripCare program, including how BioScrip employees should discuss Exjade's potential side effects with patients and which members of the Exjade Team should make the calls. For example, the Exjade marketing team at Novartis reviewed and approved the scripts for BioScrip's Exjade Team to use in discussing side effects with new Exjade patients, which indicated that Exjade therapy could "cause some discomfort initially," but that such discomfort "usually resolves over time."

X. From Fall 2007 To May 2012, Novartis Induced BioScrip To Keep Promoting Exjade Refills To Patients In Exchange For More Patient Referrals And Higher Rebates

113. By fall 2007, Novartis saw that it was reaping significant financial gains from the Exjade refill promotion program at BioScrip. For example, according to an analysis provided to the Exjade marketing team on October 11, 2007, comparing BioScrip with the other two EPASS pharmacies, BioScrip was generating – "for every patient" – "$1.5k more" in Exjade sales for Novartis. That, combined with the fact that Novartis was paying lower rebates to BioScrip as compared to the other two EPASS pharmacies, meant that Novartis received a "net benefit … of $2k" from each "patient at BioScrip." In November 2007, another comparative study showed that, for Novartis, "an Exjade patient [at] BioScrip is worth $800-$2,800 more than a patient serviced by another [pharmacy]."

114. Recognizing the economic benefit of having BioScrip call Exjade patients to recommend refills, Novartis realized that it needed to offer BioScrip additional incentives to ensure that it would continue devoting efforts to the ScripCare program. Thus, in October 2007, executives from Novartis's Exjade marketing team and managed market team began discussing with BioScrip different ways that Novartis could "reward" BioScrip for its high refill levels.

115. During those discussions, Novartis told BioScrip that, in exchange for maintaining the highest refill rate within EPASS, BioScrip could be given all or a disproportionately large share of the undesignated patient referrals. In addition, Novartis discussed the potential for paying BioScrip kickbacks under the guise of higher rebates, including rebates tied to its refill rate or the number of its refill shipments.

116. Novartis also used those discussions to ensure that BioScrip tailored its promotional efforts to Novartis's Exjade marketing strategies by disclosing key aspects of its Exjade marketing goals and tactics to BioScrip. For example, at an October 11, 2007 meeting at BioScrip's offices in Columbus, Ohio, Novartis gave BioScrip the internal Novartis sales goal for Exjade and the key Exjade marketing tactics that Novartis had developed. Then, at a January 15, 2008 meeting at Novartis's offices in Florham, New Jersey, Novartis went further and gave BioScrip a version of Novartis's 2008 Exjade marketing plan.

117. Those discussions, which continued throughout 2008, eventually led Novartis to offer three types of kickbacks to cement BioScrip's commitment to promoting Exjade refills. Most immediately, Novartis raised BioScrip's per-shipment rebate for Exjade by more than 50%, *i.e.*, from $13 to $20, starting in January 2008. As Novartis and BioScrip both understood, this was to reward BioScrip for its high refill rates in late 2007 and to ensure that BioScrip continued

to call Exjade patients to recommend refills. Further, in late 2008, Novartis again increased BioScrip's per-shipment rebate by 50%, from $20 to $30, starting on January 1, 2009.

118. In terms of patient referrals, Novartis informed BioScrip in November 2008 that, starting in January 2009 and continuing for six months, BioScrip would receive 60% of the undesignated referrals (vs. just 20% each for the other two EPASS pharmacies) due to its high refill rate as shown in the Exjade Scorecard for September 2008. This was part of Novartis's tactic of pitting the three EPASS pharmacies against each other based on their performance – in terms of how long their Exjade patients continued to order refills – as reported in the Exjade Scorecards, and then rewarding the pharmacy with the best refill performance with the most patient referrals. As deposition testimony shows, BioScrip agreed to the implementation of this scheme. Under this scheme, BioScrip was again rewarded for continuing to have, in early 2009, a high refill rate relative to the two other EPASS pharmacies in early 2009 — for the second half of 2009, BioScrip was given 40% of the undesignated patient referrals.

119. Third, in 2008, Novartis also began offering BioScrip kickbacks under the guise of "performance rebates" based on the number of Exjade orders that BioScrip shipped to patients each quarter. Specifically, under the two-tier structure agreed to by Novartis and BioScrip, Novartis paid BioScrip $7 per Exjade shipment if BioScrip's quarterly Exjade shipments exceeded the "tier 1" threshold, and $14 per shipment if the quarterly shipments exceeded the "tier 2" threshold. As explained in marketing presentations that Novartis sent to BioScrip, Novartis set those shipment thresholds based on its "National Exjade Sales Target ($)."

120. For the Exjade marketing team at Novartis, the tactic of pitting the EPASS pharmacies against each other to compete for patient referrals, together with the Exjade

performance rebate, formed the "Paying for Performance" strategy for Exjade. As Novartis marketing plans show, the Exjade marketing team not only conceived of this effort to use BioScrip and other pharmacies to promote Exjade, but also allocated part of the Exjade marketing budget to pay for some of the kickbacks offered to BioScrip in the guise of rebates.

121. This bundle of kickback incentives was sufficient to induce BioScrip to keep promoting Exjade refills in support of Novartis's marketing goals. For example, in a February 2009 strategy presentation, a BioScrip account management executive summarized what Novartis had conveyed regarding its marketing goals and tactics for Exjade, and then declared that the "BioScrip's Strategic Plan [for Exjade] is to mirror and support Novartis priorities." Specifically, the Exjade Team at BioScrip continued to call patients and – under the guise of offering education about Exjade therapy, reminders, and clinical counseling – encouraged the patients to order Exjade refills or to "restart" on Exjade.

122. These recommendations to patients to order refills or restart Exjade therapy, however, were not based on independent clinical assessments of whether a refill or restarting Exjade therapy was needed or clinically appropriate. As a former Exjade Team member acknowledged, meeting Exjade shipment goals in order to "make Novartis happy," instead of patient care, was BioScrip's top priority.

123. Thus, Exjade Team members were directed to try to get refill orders irrespective of whether such refills were needed. For example, a former CSR on the Exjade Team was told to "try to get [patients] to refill their prescription" even "if a patient already had more than a months' supply of Exjade on hand."

124. Further, even if some members of the Exjade Team had attempted to make individualized clinical assessments or to offer appropriate counseling, most of them did not have sufficient training or the requisite patient health data to do so.

125. In June 2010, Novartis sought to further align BioScrip's refill promotion efforts with Novartis's Exjade marketing goals by revising how BioScrip earned performance rebates on Exjade shipments. As Novartis records show, this rebate structure was designed to "incentivize [BioScrip] to maximize[e] length on therapy" by recommending refills to Exjade patients during the period when, according to EPASS data, they were mostly likely to discontinue therapy. Specifically, under the new arrangement, BioScrip received higher rebates if it shipped Exjade to a patient between his or her fourth and ninth months of therapy.

126. The revised rebate scheme again proved an effective inducement. For example, in 2011, Novartis compared the average number of shipments per patient dispensed by BioScrip against the average for another pharmacy that did not promote Exjade refills through purported patient education and counseling. That comparison showed that, during the first six months of therapy, BioScrip shipped 9.3 more days of Exjade than the other pharmacy. This, as Novartis recognized, translated to a 7.8 ROI, *i.e.*, return on investment from its payments to BioScrip.

XI. Novartis Knew That Its Promotion Of BioScrip's Exjade Program As Patient-Focused And Clinically Beneficial Was Belied By BioScrip's Exclusive Focus On Refill Orders And The Program's Clinical Deficiencies

A. Novartis And BioScrip Promoted BioScrip's Exjade Program As Patient-Focused And Clinically Beneficial

127. Another prong of Novartis's Exjade marketing efforts was to promote alleged benefits of the EPASS system – especially the purported clinical education and counseling offered by BioScrip and the other EPASS pharmacies – to both physicians and patients.

128. Thus, the Exjade sales representatives at Novartis were trained to tell physicians that the "#1 goal" for BioScrip and the other EPASS pharmacies was to "focus on patient and compliance." More specifically, the Exjade sales representatives were instructed to say that BioScrip and its peers offered "patient education by RNs [registered nurses] & pharmacists" as well as "counsel[ing] around side effects [of Exjade]," and that those programs not only "improve [Exjade] patient care," but also "lead to better patient outcomes."

129. To echo Novartis's marketing pitch, BioScrip also developed and distributed marketing materials to promote its Exjade program. For example, according to a 2009 BioScrip marketing brochure, BioScrip's program for Exjade (referred to as the "Iron Overload care" program in the brochure) "is patient centric, disease focused and therapy conscious." The BioScrip brochure further claimed that this program "provides consistent assessment, education, and intervention resulting in improved patient healthcare delivery."

130. Further, through the calls that BioScrip made to patients as they began Exjade therapy, Novartis and BioScrip also promoted the clinical services purportedly offered by BioScrip directly to these new Exjade patients. When members of the Exjade Team called new patients, they were directed to tell the patients that BioScrip was assigning a nurse to call the

patients to share information "about your new [Exjade] therapy, your disease and how to best manage taking your Exjade." In addition, the Exjade Team members also encouraged the patients to call BioScrip "to discuss symptoms you are experiencing or if you are concerned about a side effect." More specifically, the patients were told that the purpose of the calls was "to provide you with the best possible care while taking [] Exjade."

B. Novartis Knew That BioScrip's Exjade Program Was Designed To Generate Refills, Rather Than To Focus On Patient Care Or Clinical Benefits

131. Contrary to how it promoted the Exjade program at BioScrip, Novartis knew that BioScrip's program paid little heed to patient care and was even less equipped to deliver clinical benefits for Exjade patients.

132. Instead, as Novartis knew, BioScrip designed the program to generate Exjade refill orders so as "to make Novartis [] happy." Specifically, under the guise of having its "nurse-led team" offer patient education, reminders, and clinical counseling, BioScrip was promoting Exjade refills by pressuring patients to order refills and by giving patients biased information that emphasized the benefits of getting refills while understating the severity of the side effects. Further, even if some members of the Exjade Team at BioScrip had wished to give patients independent clinical advice, they – as Novartis was aware – lacked the requisite clinical guidance and training or the relevant patient health information to offer such advice.

133. First, as Novartis and BioScrip both understood, Novartis judged BioScrip's Exjade program according to whether the program helped Novartis achieve its sales and marketing goals for Exjade.

134. For example, in determining how to allocate patient referrals among BioScrip and the other EPASS pharmacies under its "paying for performance" strategy, Novartis measured

"performance" exclusively in terms of how long BioScrip and the other pharmacies got their Exjade patients to continue to order refills. Tellingly, while Novartis euphemistically called this measure in the Exjade Scorecard the "adherence score," Novartis and BioScrip both understood that this measure was not based on whether Exjade patients were adhering to their doctors' orders. Specifically, as a Novartis marketing executive explained, there would be "a drop in the adherence [score]" for BioScrip if some "patient[s] stopped receiving Exjade shipments because their doctors had stopped their therapy."

135. Likewise, as BioScrip's e-mails show, Novartis explained that the shipment goals for determining whether BioScrip would earn performance rebates in 2008 and 2009 were based on Novartis's "national brand [*i.e.* marketing] goals" for Exjade – more specifically, the "National Exjade Sales Target ($)."

136. BioScrip, in turn, understood that "to keep Novartis happy" meant making Exjade shipment goals, instead of caring for patients, the "top priority" for its Exjade Team. As a former Exjade Team supervisor explained under oath, Novartis's "system of tying rebates and patient referrals to the numbers of refill shipments caused [BioScrip] to be focused exclusively on the number of orders and refills, rather than on patient care." Thus, BioScrip not only pushed patients who already had too much Exjade on hand to order more refills, it also continued to ship Exjade to physicians' offices even though patients were not picking up the shipments and the doctors' offices "would become overstocked with Exjade."

137. Tellingly, there is no reference anywhere in Novartis's or BioScrip's sales or marketing materials or the talking points given to the Exjade Team at BioScrip to the fact that

Novartis was offering BioScrip a bundle of incentives tied to whether the pharmacy was meeting shipment goals based on Novartis's "Exjade sales target."

138. Further, Novartis knew that the purported patient "education" and "counseling" offered by BioScrip involved biased advice that emphasized the benefits of getting refills while understating the severity of Exjade's side effects. As a Novartis clinical executive admitted at his deposition, when a pharmacy spoke with a patient about a drug's side effects, it is "not at all" clinically appropriate to "only discuss the less serious side effects and not to refer to the more severe potential side effects;" instead, the pharmacy "should go over the severe [side effects]" and make them "more of a priority." In practice, however, Novartis had BioScrip promote Exjade refills by focusing on the less serious side effects while ignoring the more serious ones.

139. Specifically, as noted above, BioScrip created a set of talking points for its Exjade Team to use in discussing Exjade therapy with patients. With regard to side effects, the talking points indicated that Exjade could "cause some discomfort initially," but that such discomfort "usually resolves over time." In January 2008, BioScrip reviewed those talking points with Novartis, and Novartis approved them. From then until November 2010, BioScrip required the Exjade Team to follow the talking points approved by Novartis when they discussed Exjade and its side effects with patients starting Exjade therapy. As a former medical assistant on the Exjade Team explained, if patients reported "side effects [] such as diarrhea or vomiting," they were told "that they should continue taking Exjade and wait for the side effects to pass."

140. However, as noted above, numerous warnings – including the January 2010 "Black Box" warning – were added to the Exjade label between 2008 and 2010. Those warnings highlighted that Exjade was associated with severe side gastrointestinal ("GI") side effects,

including serious GI ulcerations and potentially fatal GI hemorrhages, that did not resolve over time. In addition, the warnings also discussed other severe side effects, such as renal and hepatic impairments, that could be fatal.

141. In addition, as e-mails and deposition testimony show, Novartis also withheld from BioScrip negative safety information regarding the use of Exjade among high-risk MDS patients. In July 2009, as discussed above, Novartis submitted a proposal to FDA to change the Exjade label to add a contra-indication for high-risk MDS patients. Further, by late September 2009, Novartis knew that more than 40% of the MDS patients taking Exjade were "inappropriate MDS patients," *i.e.*, high-risk MDS patients.

142. However, Novartis not only did not alert BioScrip to these safety issues directly, but also failed to share the relevant safety information after BioScrip specifically requested the information. On September 28, 2009, and after noticing a public alert indicating that the FDA was investigating adverse events, including deaths, among MDS patients taking Exjade, a BioScrip executive contacted her point of contact at Novartis for clinical issues to discuss safety issues for MDS patients using Exjade.

143. Rather than sharing the safety information being discussed within Novartis, the clinical executive at Novartis instead advised BioScrip that, with regard to MDS patients using Exjade, "there [was] no plan for a label change and patients should not discontinue taking Exjade." Further, while that clinical executive promised to "update [BioScrip] as additional information becomes available," he admitted in deposition that he did not provide any update to BioScrip regarding the "sizeable number" of "inappropriate patients who were taking Exjade."

144. Finally, Novartis also was aware that BioScrip did not provide its Exjade Team with access to the types of patient health data essential for advising an Exjade patient regarding whether to continue taking the drug. As a Novartis executive admitted at her deposition, to offer such advice, a healthcare professional needed to know, at a minimum, an Exjade patient's "serum creatinine level" and "up-to-date serum ferritin level."[4] However, as Novartis was aware, the patient information system that BioScrip used for its Exjade program did not track either type of data for most of the Exjade patients at BioScrip.

XII. Novartis And BioScrip Failed To Include Core Elements Of Their Relationship In Their Exjade Rebate Contracts

145. Novartis not only chose to hide the truth about BioScrip's Exjade program from its promotion of that program, it also did not include two key aspects of its kickback relationship with BioScrip in the rebate contracts they maintained.

146. First, neither the original 2005 BioScrip Exjade Contract nor the new contract that Novartis signed with BioScrip in June 2010 (the "2010 BioScrip Exjade Contract") referred to their shared understanding that, to keep receiving undesignated patient referrals, BioScrip had to satisfy Novartis's expectation regarding refills levels.

147. As discussed above, the Exjade kickback scheme began as a result of Novartis's imposing a PIP on BioScrip in early 2007 and conditioning BioScrip's continued access to patient referrals on its achieving a refill level that satisfied Novartis.

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[4] More specifically, the serum creatinine level indicates whether Exjade was affecting the patient's renal function, as renal impairment is a serious side effect for Exjade patients; and the serum ferritin level is relevant to assessing whether the patient continues to require therapy or has achieved his or her therapeutic goals.

148. In April 2011, after BioScrip's refill levels had dipped temporarily, Novartis again invoked this unwritten understanding to impose a "Corrective Action" plan on BioScrip and cut off the flow of undesignated patient referrals to BioScrip until it demonstrated "improvement" in its refill levels and got a sufficient number of patients who stopped ordering Exjade to "restart."

149. BioScrip responded by intensifying its focus on promoting Exjade refills to patients and launching an aggressive campaign to "intervene[e]" to restart patients on Exjade. Nonetheless, Novartis kept BioScrip from getting undesignated patient referrals for three full months. According to a May 2011 Novartis e-mail, this was intended to give BioScrip a clear "warning" on the consequence of not satisfying Novartis's expectation regarding refills levels.

150. As e-mails show, that "warning" was not lost on BioScrip. Its intensive effort to recommend refills and to get patients who stopped ordering Exjade to "restart" continued through 2011, resulting in BioScrip again having the highest refill rate among the EPASS pharmacies in late 2011. That, in turn, led Novartis to allocate 60% of the undesignated patient referrals to BioScrip starting in January 2012.

151. Second, the 2005 and 2010 BioScrip Exjade Contracts also failed to disclose anything regarding the competition for patient referrals among the EPASS pharmacies that Novartis implemented starting in late 2008, even though this was an integral part of Novartis's relationship with BioScrip.

152. As discussed above, this competition for patient referrals represented half of the bundle of incentives offered to BioScrip (performance rebates being the other half of the bundle) pursuant to Novartis's "paying for performance" strategy. As a former Novartis vice president responsible for Exjade contracting acknowledged in deposition, Novartis saw both the

competition for patient referrals and the performance rebates as "part of an overall evolution of the EPASS system." Further, as emails show, BioScrip likewise viewed the ability to get "an increased allocation of [undesignated] patients" based on higher refill levels as a basic aspect of its relationship with Novartis.

153. In drafting its contracts with BioScrip, however, Novartis chose to act as if there was no such understanding with BioScrip, as neither the 2005 nor the 2010 BioScrip Exjade Contract contained any disclosure about half of the bundle of incentives Novartis was offering to BioScrip —the ability to get more Exjade patient referrals by getting more refill orders and thus raising its refill rate in the Exjade Scorecard.

XIII. The Exjade Kickback Scheme Caused The Submission Of Thousands Of False Claims To The Intervening States' Medicaid Programs

154. As Novartis and BioScrip profited from their Exjade kickback scheme through, respectively, higher sales and the higher fees and rebates associated with additional patient referrals, the Medicaid programs of the Intervening States were made to bear the financial cost of this corrupt scheme.

155. Throughout the Exjade kickback scheme, *i.e.*, from February 2007 to May 2012, BioScrip submitted claims to the Intervening States' Medicaid programs seeking reimbursement for the Exjade shipments it dispensed. These claims were false and ineligible for reimbursement because each claim had been tainted by kickbacks.

156. Further, in seeking Medicaid reimbursement, BioScrip did not disclose its kickback relationship with Novartis or the fact that their Exjade claims resulted from a scheme that violates the AKS, a statute that BioScrip was required to, and promised to, comply with in its Medicaid enrollment forms and other certifications. In addition, neither Novartis nor

BioScrip disclosed to the Intervening States that BioScrip was promoting Exjade refills in exchange for kickbacks from Novartis in the form of patient referrals and rebates.

157. In short, by orchestrating the Exjade kickback scheme, Novartis and BioScrip caused the submissions of over tens of thousands of false claims to Medicare and Medicaid. The scheme, in turn, caused federal healthcare programs to pay out tens of millions of dollars based on the kickback-tainted false Exjade claims.

158. As detailed above, the Medicaid programs of the Intervening States paid for thousands of claims for Exjade submitted by BioScrip during the course of the Exjade kickback scheme. In total, the Medicaid programs of the Intervening States paid more than $50 million for the kickback-tainted false claims submitted in connection with the Exjade kickback scheme.

CLAIMS OF THE STATE OF GEORGIA

COUNT ONE *FALSE CLAIM*
Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

159. Plaintiff State of Georgia ("Georgia") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

160. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Georgia State Medicaid Program, which is known as the Georgia Medicaid Program: Bioscrip Pharmacy (Georgia Medicaid Provider Id. No.: 000769238A; NPI: 1437152402).

161. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), and Part I, Section 106 of the Policies and Procedures for Medicaid/Peachcare for Kids, false and fraudulent claims for payment were made

to the State of Georgia. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of O.C.G.A. § 49-4-146.1(a).

162. By reason of the false or fraudulent claims, the State of Georgia has sustained damages in a substantial amount to be determined at trial, and is entitled to damages plus a civil penalty in the amount of two times the amount of any excess benefit or payment, plus a civil penalty up to three times the amount of the excess benefit or payment.

COUNT TWO *FALSE RECORD*
Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

163. Georgia repeats and realleges each of the preceding paragraphs as if fully set forth herein.

164. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) and Part I, Section 106 of the Policies and Procedures for Medicaid/Peachcare for Kids, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Georgia, in violation of Ga. Code Ann. § 49-4-146.1(a)(2). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal Anti-Kickback Statute and regulations and Part I, Section 106 of the Policies and Procedures for Medicaid/Peachcare for Kids.

165. By reason of the false or fraudulent claims, the State of Georgia has sustained damages in a substantial amount to be determined at trial, and is entitled to damages plus a civil

penalty in the amount of two times the amount of any excess benefit or payment, plus a civil penalty up to three times the amount of the excess benefit or payment.

COUNT THREE *CONSPIRACY*
Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*

166. Georgia repeats and realleges each of the preceding paragraphs as if fully set forth herein.

167. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), and Part I, Section 106 of the Policies and Procedures for Medicaid/Peachcare for Kids, thereby causing BioScrip to submit false and fraudulent claims to the State of Georgia and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Georgia.

168. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate § 49-4-146.1(a)(3), the State of Georgia has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

COUNT FOUR
Unjust Enrichment

169. Georgia repeats and realleges each of the preceding paragraphs as if fully set forth herein.

170. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

171. By directly or indirectly obtaining funds from the State of Georgia to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Georgia, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF ILLINOIS

COUNT FIVE *FALSE CLAIM*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(A)

172. Plaintiff State of Illinois ("Illinois") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

173. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Illinois State Medicaid Program, which is known as the Illinois Medical Assistance Program: Bioscrip Pharmacy Services (Medicaid Provider No.: 3341633456003).

174. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Illinois Vendor Fraud and Kickback statute 305 ILCS 5/8A-3, and the laws, rules and regulations of the Illinois State Medicaid Program, including its provider manuals, false and fraudulent claims for payment were made to the State of Illinois. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

175. By reason of the false or fraudulent claims, the State of Illinois has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT SIX *FALSE RECORD*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(B)

176. Illinois repeats and realleges each of the preceding paragraphs as if fully set forth herein.

177. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Illinois Vendor Fraud and Kickback statute 305 ILCS 5/8A-3, and the laws, rules and regulations of the Illinois State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Illinois, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Illinois Anti-Kickback regulations and statutes and the laws, rules and regulations of the Illinois State Medicaid Program, including its provider manuals.

178. By reason of the false records or statements, the State of Illinois has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT SEVEN *CONSPIRACY*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(C)

179. Illinois repeats and realleges each of the preceding paragraphs as if fully set forth herein.

180. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Illinois Anti-Kickback Statute, 305 ILCS 5/8A-3, and the laws, rules and regulations of the Illinois State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of Illinois and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Illinois.

181. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate 740 ILCS 175/3(a)(1)(C), the State of Illinois has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT EIGHT *MEDICAID FALSE STATEMENT*
Illinois False Claims Act, 740 ILCS 175/3(a)(1)(B)

182. Illinois repeats and realleges each of the preceding paragraphs as if fully set forth herein.

183. As set forth above, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State of Illinois false or fraudulent claims for payment.

184. The State of Illinois paid such false or fraudulent claims because of the acts of Novartis.

185. By reason of Novartis' conduct, the State has been damaged in a substantial amount to be determined at trial.

186. By reason of the foregoing, Novartis is liable, pursuant to 740 ILCS 175/3(a)(1)(B) to the State of Illinois for treble damages, penalties, costs, and interest at the highest legal rate.

COUNT NINE *FRAUDULENT ACTS*
Public Assistance Fraud, 305 ILCS 5/8A-7

187. Illinois repeats and realleges each of the preceding paragraphs as if fully set forth herein.

188. 305 ILCS 5/8A-7 makes "[a]ny person, firm, corporation, agency, institution or other legal entity, other than the individual recipient, that willfully, by means of false statement or false representation, or by concealment of any material fact or by other fraudulent scheme or device on behalf of himself or others, obtains or attempts to obtain benefits or payments under this Code…shall be liable for repayment of any excess benefits or payments received and, in addition to any other penalties provided by law." Furthermore, [c]ivil recoveries…may be recoverable in court proceedings initiated by the Attorney General." 305 ILCS 5/8A-7(c).

189. By engaging in the acts and practices described above, Novartis has engaged in repeated fraudulent acts or persistent fraud in violation of 305 ILCS 5/8A-7.

190. By reason of the foregoing, Novartis is liable to the State of Illinois for damages, in an amount to be determined at trial, for the economic injuries suffered by the State of Illinois.

COUNT TEN
Unjust Enrichment

191. Illinois repeats and realleges each of the preceding paragraphs as if fully set forth herein.

192. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

193. By directly or indirectly obtaining funds from the State of Illinois to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Illinois, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF INDIANA

COUNT ELEVEN *FALSE CLAIM*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

194. Plaintiff State of Indiana ("Indiana") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

195. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Indiana State Medicaid Program, which is known as the Indiana Health Coverage Programs: BioScrip Pharmacy Services, Inc. (Indiana Medicaid Provider No.: 200130180A; NPI 1619970845), BioScrip Pharmacy, Inc. (Indiana Medicaid Provider No.: 200159820A; NPI 1316940380), and BioScrip Pharmacy, Inc. (Indiana Medicaid Provider No.: 200356880A; NPI 1427051176).

196. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24, the Indiana False Claims Act, Ind. Code § 15-11-5.5-2(b)(8), and Chapter 13, Section 2 of the Indiana Health Coverage Programs Provider Manual, false and fraudulent claims for payment were made to the State of Indiana. Accordingly, Novartis knowingly caused to be

presented false or fraudulent claims for payment or approval in violation of Ind. Code § 5-11-5.5-2(b)(1).

197. By reason of the false or fraudulent claims, the State of Indiana has sustained damages in a substantial amount to be determined at trial, and is entitled to receive a civil penalty of at least five thousand dollars ($5,000) for each false or fraudulent claim presented and up to three (3) times the amount of damages sustained by the state. In addition, the State of Indiana is entitled to the costs of a civil action brought to recover the penalties or damages. Ind. Code § 5-11-5.5-2(b).

COUNT TWELVE *FALSE RECORD*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

198. Indiana repeats and realleges each of the preceding paragraphs as if fully set forth herein.

199. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24, the Indiana False Claims Act, Ind. Code § 15-11-5.5-2(b)(8), and Chapter 13, Section 2 of the Indiana Health Coverage Programs Provider Manual, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Indiana, in violation of Ind. Code § 5-11-5.5-2(b)(2). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Indiana Anti-Kickback

regulations and statutes and the laws, rules and regulations of the Indiana State Medicaid Program, including its provider manuals.

200. By reason of the false records or statements, the State of Indiana has sustained damages in a substantial amount to be determined at trial, and is entitled to receive a civil penalty of at least five thousand dollars ($5,000) for each false or fraudulent claim presented and up to three (3) times the amount of damages sustained by the state. In addition, the State of Indiana is entitled to the costs of a civil action brought to recover the penalties or damages. Ind. Code § 5-11-5.5-2(b).

COUNT THIRTEEN *CONSPIRACY*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*

201. Indiana repeats and realleges each of the preceding paragraphs as if fully set forth herein.

202. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24, the Indiana False Claims Act, Ind. Code § 15-11-5.5-2(b)(7), and Chapter 13, Section 2 of the Indiana Health Coverage Programs Provider Manual, thereby causing BioScrip to submit false and fraudulent claims to the State of Indiana and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Indiana.

203. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate Ind. Code § 5-11-5.5-2(b)(1) or (2)

the State of Indiana has sustained damages in a substantial amount to be determined at trial, and is entitled to receive a civil penalty of at least five thousand dollars ($5,000) for each false or fraudulent claim and up to three (3) times the amount of damages sustained by the state. In addition, the State of Indiana is entitled to the costs of a civil action brought to recover the penalties or damages. Ind. Code § 5-11-5.5-2(b).

COUNT FOURTEEN *MEDICAID FRAUD*
Indiana Code § 35-43-5-7.1

204. Indiana repeats and realleges each of the preceding paragraphs as if fully set forth herein.

205. Indiana's Medicaid Fraud Statute, Ind. Code § 35-43-5-7.1, provides, in pertinent parts, that a person who knowingly or intentionally: (1) files a Medicaid claim, including an electronic claim, in violation of Ind. Code 12-15; (2) obtains payment from the Medicaid program under Ind. Code 12-15 by means of a false or misleading oral or written statement or other fraudulent means; . . . or (5) conceals information for the purpose of applying for or receiving unauthorized payments from the Medicaid program, commits Medicaid fraud, a Class D felony. The offense is enhanced to a Class C felony if the market value of the offense is at least one hundred thousand dollars ($100,000).

206. Under Indiana law, a person who knowingly or intentionally aids, induces, or causes another person to commit an offense commits that offense. Ind. Code § 35-41-2-4.

207. As set forth above, from February 2007 to May 2012, Novartis induces or caused BioScrip, by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24. Therefore, Novartis by operation of law filed Medicaid claims in

violation of Ind. Code 12-15, obtained payment from the Indiana Medicaid program by means of false or misleading oral or written statements or other fraudulent means, and concealed information for the purpose of applying for or receiving unauthorized payments from the Medicaid program, all in violation of Ind. Code § 35-43-5-7.1.

208. By reason of Novartis' conduct, the State has been damaged and has suffered a pecuniary loss as a result of a violation of Ind. Code 35-43 in a substantial amount to be determined at trial.

209. By reason of the foregoing, Novartis is liable, pursuant to Ind. Code § 34-24-3-1 to the State of Indiana for:

> (1) an amount not to exceed three times actual damages;
> (2) the costs of the action;
> (3) a reasonable attorney's fee;
> (4) Actual travel expenses that are not otherwise reimbursed under subdivisions (1) through (3) and are incurred by the person suffering loss to: (A) have the person suffering loss or an employee or agent of that person file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) provide witnesses to testify in court proceedings related to the recovery of a judgment under this chapter;
> (5) A reasonable amount to compensate the person suffering loss for time used to: (A) file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) travel to and from activities described in clause (A);
> (6) Actual direct and indirect expenses incurred by the person suffering loss to compensate employees and agents for time used to: (A) file papers and attend court proceedings related to the recovery of a judgment under this chapter; or (B) travel to and from activities described in clause (A);
> (7) All other reasonable costs of collection.

COUNT FIFTEEN *THEFT*
Indiana Code § 35-43-4-2

210. Indiana repeats and realleges each of the preceding paragraphs as if fully set forth herein.

211. The Indiana Anti-Kickback Statute, Ind. Code § 12-15-24-2, provides:

> A person who furnishes items or services to an individual for which payment is or may be made under this chapter and who solicits, offers, or receives a:
> (1) kickback or bribe in connection with the furnishing of the items or services or the making or receipt of the payment; or
> (2) rebate of a fee or charge for referring the individual to another person for the furnishing of items or services; commits a Class A misdemeanor.

212. Novartis has provided or offered kickbacks to BioScrip and BioScrip has received kickbacks in connection with the furnishing of items for which payment was made by the Indiana Medicaid program under Ind. Code 12-15 in violation of Ind. Code §12-15-24-2. Neither Novartis nor BioScrip had disclosed the kickbacks to the Indiana Medicaid program.

213. As a proximate result of the actions of Novartis, BioScrip knowingly or intentionally obtained or possessed property of the State of Indiana without its consent or by creating or confirming a false impression in the Indiana Medicaid program that the claims it submitted for Exjade were not in violation of the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24-2.

214. The Indiana Anti-Kickback Statute, Ind. Code § 12-15-24-1, also provides:

> Evidence that a person or provider received money or other benefits as a result of a violation of:
> (1) a provision of this article; or
> (2) a rule established by the secretary under this article;
> constitutes prima facie evidence, for purposes of IC 35-43-4-2, that the person or provider intended to deprive the state of a part of the value of the money or benefits.

215. Novartis provided and BioScrip received kickbacks in violation of Article 12-15, therefore such payments constitute prima facie evidence for the purposes of Ind. Code § 35-43-4-2, that BioScrip intended to deprive the State of Indiana a part of the value of the money or benefits.

216. Ind. Code § 35-43-4-2(a) provides "[a] person who knowingly or intentionally exerts unauthorized control over the property of another person, with intent to deprive the other person of any part of its value or use, commits theft, a Class D felony." Exertion of control is defined as "to obtain, take, carry ... or possess property." Ind. Code § 35-43-4-1(a). The control "is 'unauthorized' if is exerted: (1) Without the other person's consent; ... (4) By creating or confirming a false impression in the other person ... " Ind. Code § 35-43-4-1(b).

217. Under Indiana law, a person who knowingly or intentionally aids, induces, or causes another person to commit an offense commits that offense. Ind. Code § 35-41-2-4.

218. As set forth above, from February 2007 to May 2012, Novartis induces or caused BioScrip, by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the Indiana Anti-Kickback Statute, Ind. Code § 12-15-24. Therefore, Novartis by operation of law knowingly or intentionally exerted unauthorized control over the property of the state, with intent to deprive the state of any part of its value or use, i.e., committed theft.

219. By reason of Novartis' conduct, the State has been damaged and has suffered a pecuniary loss as a result of a violation of Ind. Code 35-43 in a substantial amount to be determined at trial and therefore is entitled to the remedies provided by Ind. Code § 34-24-3-1.

COUNT SIXTEEN
Unjust Enrichment

220. Indiana repeats and realleges each of the preceding paragraphs as if fully set forth herein.

221. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

222. By directly or indirectly obtaining funds from the State of Indiana to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Indiana, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF MARYLAND

COUNT SEVENTEEN *FALSE CLAIM*
Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

223. Plaintiff State of Maryland ("Maryland") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

224. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Maryland State Medicaid Program, which is known as the Maryland Medical Assistance Program: Bioscrip Pharmacy Inc., Medicaid Provider No.: 143710100) and Bioscrip Pharmacy Services (Medicaid Provider No.: 812266100).

225. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), and the laws, rules and regulations of Maryland and the Maryland State Medicaid Program, including its provider manuals, false and fraudulent

claims for payment were made to the State of Maryland. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

226. By reason of the false or fraudulent claims, the State of Maryland has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of up to $10,000 for each violation.

COUNT EIGHTEEN *FALSE RECORD*
Maryland False Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 through 2-611

227. Maryland repeats and realleges each of the preceding paragraphs as if fully set forth herein.

228. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), and the laws, rules and regulations of the Maryland State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Maryland, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Maryland Anti-Kickback regulations and statutes and the laws, rules and regulations of Maryland and the Maryland State Medicaid Program, including its provider manuals.

229. By reason of the false records or statements, the State of Maryland has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of up to $10,000 for each violation.

COUNT NINETEEN *CONSPIRACY*
Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

230. Maryland repeats and realleges each of the preceding paragraphs as if fully set forth herein.

231. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), and the laws, rules and regulations of Maryland and the Maryland State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of Maryland and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Maryland.

232. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate Md. Code, Health-Gen. § 2-602(a)(3), the State of Maryland has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of up to $10,000 for each violation.

COUNT TWENTY *MEDICAID FALSE STATEMENT*
Maryland False Claims Act, Md. Code, Health-Gen. §§ 2-601 through 2-611

233. Maryland repeats and realleges each of the preceding paragraphs as if fully set forth herein.

234. As set forth above, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State of Maryland false or fraudulent claims for payment.

235. The State of Maryland paid such false or fraudulent claims because of the acts of Novartis.

236. By reason of Novartis' conduct, the State has been damaged in a substantial amount to be determined at trial.

237. By reason of the foregoing, Novartis is liable, pursuant to Md. Code, Health-Gen. §§ 2-602(a)(2) to the State of Maryland for treble damages, penalties, costs, and interest at the highest legal rate.

COUNT TWENTY-ONE
Intentional Misrepresentation
(Fraud)

238. Maryland repeats and realleges each of the preceding paragraphs as if fully set forth herein.

239. Novartis knowingly made and/or caused to be made, a false material representation to the State of Maryland regarding the services provided to various recipients.

240. Novartis Defendant knew the claims submitted for payment were false or fraudulent or, in the alternative, submitted the claims for payment with reckless disregard for the truth of the contents thereof.

241. Novartis submitted the false or fraudulent claims for the purpose of defrauding the State of Maryland.

242. The State of Maryland justifiably relied upon the Defendant's misrepresentations and sustained significant monetary damages as a result of that reliance.

243. By reason of the foregoing, Novartis is liable to the State of Maryland for compensatory damages, punitive damages, penalties, costs, and interest at the highest legal rate.

COUNT TWENTY-TWO
Constructive Fraud

244. The allegations contained in the preceding paragraphs are incorporated as if fully set forth herein.

245. As a party to the Maryland Medicaid Provider Agreement, Novartis owed the State of Maryland a duty of care to comply with all of the requirements of the Maryland Medical Assistance Program as well as any other applicable regulations, transmittals, and guidelines, which includes not submitting false and/or fraudulent claims for payment.

246. Novartis owed the State of Maryland both a legal and equitable duty to refrain from submitting false claims to the Medical Assistance Program for payment.

247. Novartis breached that duty when it submitted false or fraudulent claims for payment as discussed herein.

248. Novartis Medicaid provider maintained a confidential relationship with the State of Maryland.

249. Novartis's actions described hereinabove violated the confidential relationship that existed between it and the State of Maryland.

250. As a result of Novartis's breach of both the legal and equitable duties, the State of Maryland sustained significant monetary damages.

251. By reason of the foregoing, Novartis is liable to the State of Maryland for compensatory damages, punitive damages, penalties, costs, and interest at the highest legal rate.

COUNT TWENTY-THREE
Unjust Enrichment

252. The allegations contained in the preceding paragraphs are incorporated as if fully set forth herein.

253. As a result of the conduct described herein, Novartis was paid Medicaid funds to which it was not entitled.

254. Novartis knew and appreciated that it was paid Medicaid funds to which it was not entitled.

255. Novartis's acceptance or retention of the Medicaid funds under the circumstances is such that it would be inequitable to allow Novartis to retain the Medicaid funds without the paying of value in return.

256. As a consequence of the acts set forth above, Novartis was unjustly enriched at the expense of the State of Maryland.

257. In equity and good conscience, Novartis should not be permitted to retain monies wrongfully received and retained from the State of Maryland.

258. By reason of the foregoing, Novartis is liable to the State of Maryland for compensatory damages, punitive damages, penalties, costs, and interest at the highest legal rate.

CLAIMS OF THE STATE OF MICHIGAN

COUNT TWENTY-FOUR *KICKBACK*
Michigan Medicaid False Claims Act, MCL 400.604

259. Plaintiff State of Michigan ("Michigan") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

260. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Michigan State Medicaid Program, which is known as the Michigan Medicaid State Plan: BioScrip Pharmacy Services (NPI No.: 1619970845) and BioScrip Pharmacy (NPI No.: 1417950544).

261. Novartis offered kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in connection with the furnishing of goods or services for which payment was made, in whole or in part, pursuant to the Michigan Medicaid Program established under the social welfare act.

262. Novartis and BioScrip made or received the payment, or rebate of a fee or charge for referring an individual to another person for the furnishing of the goods and services in violation of MCL 400.604, and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals. Accordingly, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Michigan.

263. By reason of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5, 000 to $10,000 for each violation. MCL 400.612, as amended.

COUNT TWENTY-FIVE *FALSE CLAIM*
Michigan Medicaid False Claims Act, MCL 400.607(1)

264. Michigan repeats and realleges each of the preceding paragraphs as if fully set forth herein.

265. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), MCL 400.604 and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Michigan, in violation of MCL § 400.607(1). The false records or statements or omissions were BioScrip's false certifications and representations that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Michigan Anti-kickback regulations and statutes and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals.

266. By reason of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5, 000 to $10,000 for each violation. MCL 400.612, as amended.

COUNT TWENTY-SIX *FALSE RECORD*
Michigan Medicaid False Claims Act, MCL 400.607(3)

267. Michigan repeats and realleges each of the preceding paragraphs as if fully set forth herein.

268. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Michigan Anti-Kickback Statute, MCL 400.604, and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Michigan, in violation of MCL § 400.607(3). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Michigan Anti-Kickback regulations and statutes and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals.

269. By reason of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5,000 to $10,000 for each violation. MCL 400.612, as amended.

COUNT TWENTY-SEVEN *CONSPIRACY*
Michigan Medicaid False Claims Act, MCL 400.606

270. Michigan repeats and realleges each of the preceding paragraphs as if fully set forth herein.

271. As set forth above, from February 2007 to May 2012, Novartis entered into an agreement, combination, or conspiracy with BioScrip defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act, offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or

to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), MCL 400.604, and the laws, rules and regulations of the Michigan State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of Michigan and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Michigan, in violation of MCL 400.606.

272. By reason of the false or fraudulent claims made by the defendants, the State of Michigan suffered damages and therefore is entitled full amount received plus triple the amount of damages suffered by the state, pursuant to MCL 400.612, plus a civil penalty of $5, 000 to $10,000 for each violation. MCL 400.612, as amended.

COUNT TWENTY-EIGHT
Common Law Fraud

273. Michigan repeats and realleges each of the preceding paragraphs as if fully set forth herein.

274. Defendant caused to be made material and false representations with knowledge of their falsity or reckless disregard for their truth, with the intention that the State of Michigan act upon the misrepresentations to its detriment. The State of Michigan acted in justifiable reliance upon these misrepresentations and made payments.

275. As a result of these payments, the State of Michigan has been damaged in an amount to be determined at trial.

COUNT TWENTY-NINE
Unjust Enrichment

276. Michigan repeats and realleges each of the preceding paragraphs as if fully set forth herein.

277. Michigan Medicaid reimbursed for the subject drugs and would not have done so if defendant had not engaged in the unlawful conduct.

278. It would be inequitable for Novartis to retain any of its ill-gotten gains earned as a result of the scheme alleged herein.

279. By directly or indirectly obtaining funds from the State of Michigan to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts obtained because of Novartis's unlawful scheme, or the proceeds therefrom, which are to be determined at trial, common law compensatory damages in an amount to be determined, together with costs and interest, and all such relief as may be just and proper, to the State of Michigan.

CLAIMS OF THE STATE OF NEW JERSEY

COUNT THIRTY *FALSE CLAIM*
New Jersey False Claims Act, N.J.S.A. 32C-1, et seq.

280. Plaintiff State of New Jersey ("New Jersey") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

281. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the New Jersey State Medicaid Program, which is known as the New Jersey Department of Human Services, Division of Medical Assistance and Health Services (hereafter referred to as the "New Jersey State Medicaid Program"): Bioscrip Infusion Services,

LLC (Medicaid Provider No.: 0064122); Bioscrip Pharmacy Services, Inc. (Medicaid Provider No.: 0098817); and, Bioscrip (Medicaid Provider No.: 6754201).

282. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the New Jersey Anti-Kickback Statute, N.J.S.A 30:4D-17(c), and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals, false and fraudulent claims for payment were made to the State of New Jersey. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of N.J.S.A § 2A:32C-3a.

283. By reason of the false or fraudulent claims, the State of New Jersey has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT THIRTY-ONE *FALSE RECORD*
New Jersey False Claims Act, N.J.S.A. 2A:32C-3b

284. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

285. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the New Jersey Anti-Kickback Statute, N.J.S.A and 30:4D-17(c), and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of New Jersey, in violation of N.J. Stat. Ann. § 2A:32C-3b. The false records or statements or

omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and New Jersey Anti-Kickback regulations and statutes and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals.

286. By reason of the false records or statements, the State of New Jersey has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT THIRTY-TWO *CONSPIRACY*
New Jersey False Claims Act, N.J.S.A. 2A:32C-3c

287. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

288. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the New Jersey Anti-Kickback Statute, N.J.S.A. § 30:4D-17(c), and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of New Jersey and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of New Jersey in violation of N.J.S.A. §2A:32C-3c.

289. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate the above-referenced anti-kickback

statutes, the State of New Jersey has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,500 to $11,000 for each violation.

COUNT THIRTY-THREE *MEDICAID FALSE STATEMENT*
N.J.S.A. § 30:4D-17(b)

290. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

291. As set forth above, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State of New Jersey false or fraudulent claims for payment.

292. The State of New Jersey paid such false or fraudulent claims because of the acts of Novartis.

293. By reason of Novartis' conduct, the State has been damaged in a substantial amount to be determined at trial.

294. By reason of the foregoing, Novartis is liable, pursuant to N.J.S.A. § 30:4D-17(b) to the State of New Jersey for treble damages, penalties, costs, and interest at the highest legal rate.

COUNT THIRTY-FOUR *CONVERSION*
Conversion

295. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

296. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to

purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the New Jersey Anti-Kickback Statute, N.J.S.A. § 30:4D-17(c), and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of New Jersey and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of New Jersey.

297. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid by New Jersey Medicaid, Novartis received Medicaid funds for the payment of Exjade which are properly due to the State of New Jersey.

298. The acts and practices of Novartis complained of herein, including expenditures by the State of New Jersey for purchases of Exjade by and through Bioscrip, constitute a conversion of state funds spent on such purchases. By reason of the foregoing, the State is entitled to recoup from Novartis in an amount yet to be determined all such funds, plus costs, expenses, and the maximum amount of interest available under law.

COUNT THIRTY-FIVE
Common Law Fraud

299. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

300. Defendant caused to be made material and false representations concerning its relationship with BioScrip, and its offer and payment of kickbacks in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the New Jersey Anti-Kickback Statute, N.J.S.A. § 30:4D-17(c), and the laws, rules and regulations of the New Jersey State Medicaid Program, including its provider manuals.

301. Defendant's material and false representations were made with knowledge of their falsity or reckless disregard for their truth, with the intention that the State of New Jersey act upon the misrepresentations to its detriment. The State of New Jersey reasonably relied upon these misrepresentations and reimbursed tainted claims for Exjade.

302. As a result of these payments, the State of New Jersey has been damaged in an amount to be determined at trial.

COUNT THIRTY-SIX
Unjust Enrichment

303. New Jersey repeats and realleges each of the preceding paragraphs as if fully set forth herein.

304. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

305. By directly or indirectly obtaining funds from the State of New Jersey to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of New Jersey, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF NEW YORK

COUNT THIRTY-SEVEN *FALSE CLAIM*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(a)

306. Plaintiff State of New York ("New York") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

307. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the New York State Medical Assistance Program, which is

known as the New York State Medicaid Program: Bioscrip Pharmacy NY Inc. (N.Y. Medicaid Provider No.: 02244640) and Bioscrip Pharmacy Inc. (N.Y. Medicaid Provider No. 02731964).

308. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R. § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law § 366-d(2), and the laws, rules and regulations of the New York State Medicaid Program, including its provider manuals, false and fraudulent claims for payment were made to the State of New York. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of N.Y. State Fin. Law § 189(1)(a).

309. By reason of the false or fraudulent claims, the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

COUNT THIRTY-EIGHT *FALSE RECORD*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(b)

310. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

311. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R. § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law § 366-d(2), and the laws, rules and regulations of the New York State Medicaid Program, including its provider manuals, Novartis knowingly caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for

payment submitted to the State of New York, in violation of N.Y. State Fin. Law § 189(1)(b). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and New York Anti-Kickback regulations and statutes and the laws, rules and regulations of the New York State Medicaid Program, including its provider manuals.

312. By reason of the false records or statements, the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

COUNT THIRTY-NINE *CONSPIRACY*
New York False Claims Act, N.Y. State Fin. Law § 189(1)(c)

313. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

314. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R. § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law § 366-d(2), and the laws, rules and regulations of the New York State Medicaid Program, including its provider manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of New York and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of New York.

315. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get submitted and allowed or paid or by reasons of their conspiracy to violate N.Y. State Fin. Law § 189(1)(a) and N.Y. State Fin. Law § 189(1)(b), the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $6,000 to $12,000 for each violation.

COUNT FORTY *FALSE STATEMENT*
New York Social Services Law § 145-b

316. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

317. As set forth above, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State of New York false or fraudulent claims for payment.

318. The State of New York paid such false or fraudulent claims because of the acts of Novartis.

319. By reason of Novartis' conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

320. By reason of the foregoing, Novartis is liable, pursuant to N.Y. Social Services Law §145-b, to the State of New York for treble damages, penalties, costs, and interest at the highest legal rate.

COUNT FORTY-ONE *REPEATED FRAUDULENT ACTS*
New York Executive Law § 63(12)

321. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

322. N.Y. Executive Law § 63(12) makes "repeated fraudulent . . . acts of . . . persistent fraud . . . in the carrying on, conducting or transaction of business actionable by the Attorney General."

323. By engaging in the acts and practices described above, Novartis has engaged in repeated fraudulent acts or persistent fraud in violation of N.Y. Executive Law § 63(12).

324. By reason of the foregoing, Novartis is liable to the State of New York for damages, in an amount to be determined at trial, for the economic injuries suffered by the State of New York.

COUNT FORTY-TWO *MISAPPROPRIATION OF PUBLIC PROPERTY*
New York Executive Law § 63-c

325. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

326. The acts and practices of Novartis complained of herein constitute a misappropriation of public property, in violation of N.Y. Executive Law § 63-c. By reason of the foregoing, the State of New York is entitled to restitution from Novartis in an amount yet to be determined, plus costs, expenses, and the maximum amount of interest available under law.

COUNT FORTY-THREE
Unjust Enrichment

327. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

328. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

329. By directly or indirectly obtaining funds from the State of New York to which it was not entitled, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of New York, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF OKLAHOMA

COUNT FORTY-FOUR *KICKBACKS*
Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56, §§ 1005-1007

330. The State of Oklahoma repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

331. Novartis solicited or accepted a benefit, pecuniary benefit, or kickback in connection with goods or services claimed by BioScrip and paid by the Oklahoma Medicaid Program, in violation of Okla. Stat. tit. 56, § 1005(A)(6), by providing kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade, which was then billed to and paid for by the Oklahoma Medicaid Program.

332. By virtue of this conduct, Oklahoma did in fact pay said claims to its detriment. Defendant is liable to the State of Oklahoma, pursuant to Okla. Stat. tit. 56, § 1005(A)(6). Defendant owes damages to Oklahoma as provided for in Okla. Stat. tit. 56, § 1007, for full restitution, plus a civil penalty of two times the amount of restitution, interest at the maximum legal rate, the costs of investigation, litigation, and attorney fees, in addition to other penalties provided by law.

COUNT FORTY-FIVE *FALSE CLAIM*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

333. Plaintiff State of Oklahoma ("Oklahoma") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

334. During the period February 2007 to May 2012, the following BioScrip entity submitted claims for Exjade to the Oklahoma State Medicaid Program, which is known as the Oklahoma Health Care Authority, and SoonerCare: BioScrip Pharmacy Services (OHCA Provider #100244680A; NPI 1619970845).

335. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and 1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider manuals and provider agreements, false and fraudulent claims for payment were made to the State of Oklahoma. Accordingly, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented false or fraudulent claims for payment or approval in violation of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)(1).

336. By reason of the false or fraudulent claims, the State of Oklahoma did in fact pay said claims and has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT FORTY-SIX *FALSE RECORD OR STATEMENT*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

337. Oklahoma repeats and realleges each of the preceding paragraphs as if fully set forth herein.

338. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and 1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider agreements and manuals, Novartis knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Oklahoma, in violation of the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)(2). The false records or statements or omissions were BioScrip's false certifications, representations, or omissions that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Oklahoma Anti-Kickback regulations and statutes and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider agreements and manuals.

339. By reason of the false records or statements, the State of Oklahoma did approve false or fraudulent claims and has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT FORTY-SEVEN *CONSPIRACY*
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1

340. Oklahoma repeats and realleges each of the preceding paragraphs as if fully set forth herein.

341. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and 1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider agreements and manuals, thereby causing BioScrip to submit false and fraudulent claims to the State of Oklahoma and causing BioScrip to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Oklahoma.

342. By virtue of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)(3), the State of Oklahoma has in fact paid or allowed false or fraudulent claims and has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT FORTY-EIGHT *MEDICAID PROGRAM INTEGRITY VIOLATION*
Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56, §§ 1005-1007

343. The State of Oklahoma repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

344. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and 1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider manuals and provider agreements, false and fraudulent claims for payment were made to the State of Oklahoma. Accordingly, Defendant knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, made or caused to be made false claims, by omission or commission, to the Oklahoma Medicaid Program for payment or approval, in violation of Okla. Stat. tit. 56, § 1005(A)(1). The Oklahoma Medicaid Program did in fact pay these false claims.

345. By virtue of this conduct, Defendant is liable to the State of Oklahoma, as provided for in Okla. Stat. tit. 56, § 1007, for full restitution, plus a civil penalty of two times the amount of restitution, interest at the maximum legal rate, the costs of investigation, litigation, and attorney fees, in addition to other penalties provided by law.

COUNT FORTY-NINE *FRAUD*
Common Law Fraud

346. The State of Oklahoma repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

347. By virtue of the above acts and omissions, Novartis knowingly, or with reckless disregard for the truth, caused to be made material and false or fraudulent claims, statements, and representations, and omitting material facts, concerning its relationship with BioScrip and its offer and payment of kickbacks in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and

1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider agreements and manuals, to the Oklahoma Medicaid system to induce payment or approval of false and fraudulent claims.

348. Defendant Novartis intended that the State of Oklahoma rely upon these material misrepresentations and omissions. Oklahoma justifiably relied on the material and false or fraudulent claims, statements, representations and/or omissions Novartis caused to be submitted. The State of Oklahoma, unaware of the false and fraudulent representations, statements, claims and/or omissions Novartis caused to be submitted has, to its detriment, paid improper and fraudulent claims that would not have been paid but for Defendant's improper conduct.

349. By virtue of this conduct, Defendant is liable to the State of Oklahoma for damages, punitive damages pursuant to Okla. Stat. tit. 23, § 9.1, and any other relief the Court deems appropriate.

COUNT FIFTY
Civil Conspiracy

350. Oklahoma repeats and realleges each of the preceding paragraphs as if fully set forth herein.

351. As set forth above, from February 2007 to May 2012, Novartis unlawfully and fraudulently conspired with BioScrip by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Oklahoma Medicaid Program Integrity Act, Okla. Stat. tit. 56 §§ 1002 and 1005(A)(6), and the laws, rules and regulations of the Oklahoma State Medicaid Program, including its provider agreements and manuals, thereby causing BioScrip to unlawfully submit false and fraudulent claims to the State of Oklahoma and

causing BioScrip to unlawfully make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of Oklahoma.

352. By virtue of the false or fraudulent claims Novartis and BioScrip unlawfully conspired to get allowed or paid, or by reasons of their conspiracy to violate the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)(3), the State of Oklahoma has sustained actual damages in a substantial amount to be determined at trial.

COUNT FIFTY-ONE
Unjust Enrichment

353. Oklahoma repeats and realleges each of the preceding paragraphs as if fully set forth herein.

354. This is a claim for the recovery of monies by which Novartis has been unjustly enriched.

355. By directly or indirectly obtaining funds from the State of Oklahoma to which Novartis was not entitled, and to Oklahoma's detriment, Novartis has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, in restitution or disgorgement, which are to be determined at trial, to the State of Oklahoma, plus costs, expenses, and the maximum amount of interest available under law.

CLAIMS OF THE STATE OF WISCONSIN

COUNT FIFTY-TWO
Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(a)
(Medical Assistance Fraud)

356. Plaintiff State of Wisconsin ("Wisconsin") repeats and realleges each of the preceding paragraphs as if fully set forth herein.

357. During the period February 2007 to May 2012, the following BioScrip entities submitted claims for Exjade to the Wisconsin Medicaid Program: Bioscrip Pharmacy, Inc. (Wisconsin Medicaid Pharmacy Provider No.: 33254300) and Bioscrip Pharmacy Services, Inc. (Wisconsin Medicaid Pharmacy Provider No.: 33292400).

358. As a result of Novartis's kickbacks and offers of kickbacks to BioScrip to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Wisconsin Anti-Kickback Statute, Wis. Stat. § 49.49(2)(a) and 49.49(2)(b) and the laws, rules and regulations of the Wisconsin Medicaid Program, including its provider manuals, Novartis knowingly presented or caused to be presented to any officer, employee, or agent of this state a false claim for medical assistance in violation of Wis. Stat. § 20.931(2)(a).

359. By reason of the false or fraudulent claims, the State of Wisconsin has sustained damages in a substantial amount to be determined at trial in an amount reasonably necessary to remedy the harmful effect of the defendant's conduct, and seeks an injunction enjoining the defendant from continuing the unlawful practices described above, forfeitures in the amount of not less than $5,000 and not more than $10,000 for each false claim, treble damages, reasonable and necessary costs of investigation and prosecution of this case including reasonable attorneys' fees, and all applicable assessments and surcharges, including surcharges imposed under Wis. Stat. ch. 814.

COUNT FIFTY-THREE
Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(b)
(False Record)

360. Wisconsin repeats and realleges each of the preceding paragraphs as if fully set forth herein.

361. As a result of Novartis's kickbacks and offers of kickbacks to induce BioScrip to purchase, to order, and to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Wisconsin Anti-Kickback Statute, Wis. Stat. § 49.49(2)(a) and 49.49(2)(b) and the laws, rules and regulations of the Wisconsin Medicaid Program, including its provider manuals, Novartis knowingly made, used, or caused to made or used by BioScrip, false records or statements to obtain approvals or payments of false claims for medical assistance, to wit: statements that the services were provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal and Wisconsin Anti-Kickback regulations and statutes and the laws, rules and regulations of the Wisconsin Medicaid Program, including its provider manuals, in violation of Wis. Stat. § 20.931(2)(b).

362. By reason of the false records or statements, the State of Wisconsin has sustained damages in a substantial amount to be determined at trial in an amount reasonably necessary to remedy the harmful effect of the defendant's conduct, and seeks an injunction enjoining the defendant from continuing the unlawful practices described above, forfeitures in the amount of not less than $5,000 and not more than $10,000 for each false claim, treble damages, reasonable and necessary costs of investigation and prosecution of this case including reasonable attorneys' fees, and all applicable assessments and surcharges, including surcharges imposed under Wis. Stat. ch. 814.

COUNT FIFTY-FOUR
Wisconsin False Claims For Medical Assistance Law, Wis. Stat. § 20.931(2)(c)
(Conspiracy)

363. Wisconsin repeats and realleges each of the preceding paragraphs as if fully set forth herein.

364. As set forth above, from February 2007 to May 2012, Novartis conspired with BioScrip to defraud Wisconsin by obtaining allowance or payment of a false claim for medical assistance , to wit: by offering and paying BioScrip kickbacks in exchange for, or to induce, BioScrip to purchase, to order, or to recommend Exjade in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), the Wisconsin Anti-Kickback Statute, the Wisconsin Anti-Kickback Statute, Wis. Stat. § 49.49(2)(a) and 49.49(2)(b), and the laws, rules and regulations of the Wisconsin Medicaid Program, including its provider manuals, in violation of Wis. Stat. § 20.931(2)(c).

365. By virtue of such actions Novartis and BioScrip conspired to obtain allowance or payment of a false claim contrary to Wis. Stat. § 20.931(2)(c), and the State of Wisconsin has therefore sustained damages in a substantial amount to be determined at trial in an amount reasonably necessary to remedy the harmful effect of the defendant's conduct, and seeks an injunction enjoining the defendant from continuing the unlawful practices described above, forfeitures in the amount of not less than $5,000 and not more than $10,000 for each false claim, treble damages, reasonable and necessary costs of investigation and prosecution of this case including reasonable attorneys' fees, and all applicable assessments and surcharges, including surcharges imposed under Wis. Stat. ch. 814.

COUNT FIFTY-FIVE
Unjust Enrichment

366. Wisconsin repeats and realleges each of the preceding paragraphs as if fully set forth herein.

367. This is a claim for the recovery of monies by which Novartis has been unjustly enriched by directly or indirectly obtaining funds from the State of Wisconsin to which it was not entitled.

368. As set forth above, the Wisconsin Medicaid Program issued Medicaid reimbursements to BioScrip based on false or fraudulent claims for Exjade, which BioScrip dispensed as a result of kickbacks offered or paid by Novartis and in violation of federal and state laws and regulations, including, but not limited to, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the Wisconsin Medical Assistance anti-kickback provisions, Wis. Stats. §§ 49.49(2)(a), 49.49(2)(b).

369. Novartis has been unjustly enriched due to its receipt of monies based on BioScrip's dispensing Exjade as a result of kickbacks offered or paid by Novartis such that, in equity and good conscience, Novartis and BioScrip should not retain such monies, the amount of which is to be determined at trial.

370. By reason of the defendants' unjust enrichment, the State of Wisconsin is entitled to disgorgement of all monies that the defendants earned as a result of the Exjade kickback scheme and/or imposition of a constructive trust in favor of the State of Wisconsin on those monies.

371. The State of Wisconsin has sustained damages in a substantial amount to be determined at trial in an amount reasonably necessary to remedy the harmful effect of the

defendant's conduct, and seeks an injunction enjoining Novartis from continuing the unlawful practices described above, reasonable and necessary costs of investigation and prosecution of this case including reasonable attorneys' fees, and appropriate penalty assessments and surcharges including surcharges imposed under Wis. Stat. ch. 814.

PRAYER FOR RELIEF

WHEREFORE, the undersigned Intervening States respectfully request this Court to enter judgment for the Intervening States and against Defendant Novartis on each count of this First Amended Complaint, to impose damages, penalties, interest, costs, and expenses as described above and to the full extent allowed by law, and for all such further relief as may be just and proper.

Dated: September 18, 2014

Respectfully submitted,

THE STATE OF GEORGIA
By its attorney,
SAM OLENS
Attorney General

By: /s/Elizabeth White
Elizabeth White
Assistant Attorney General
Georgia Medicaid Fraud Control Unit
200 Piedmont Avenue, S.E.
West Tower, 19th Floor
Atlanta, GA 30334
Phone: (404) 656-4145
Fax: (404) 657-7441
Email: EWhite@law.ga.gov

THE STATE OF ILLINOIS
By its attorney,
LISA MADIGAN
Attorney General

By: /s/ Clemon D. Ashley
Clemon D. Ashley
Elisa C. Hamilton
Assistant Attorneys General
Office of the Illinois Attorney General
100 W. Randolph St., 12th Floor
Chicago, Illinois, 60601
Phone: (312) 793-0867
Fax: (312) 814-5366
Email: CAshley@atg.state.il.us
Email: EHamilton@atg.state.il.us

THE STATE OF INDIANA
By its attorney,
GREG ZOELLER
Attorney General

By: /s/ Lawrence J. Carcare
Lawrence J. Carcare II
Deputy Attorney General
Medicaid Fraud Control Unit
Indiana Office of the Attorney General
8005 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 915-5319
Fax: (317) 232-7979
Email: Lawrence.Carcare@atg.in.gov

THE STATE OF MARYLAND
By its attorney,
DOUG GANSLER
Attorney General

By: /s/ Jeremy Dykes
Jeremy Dykes
Assistant Attorney General
Medicaid Fraud Control Unit
Maryland Office of the Attorney General
Phone: (410) 576-6528
Fax: (410) 576-6314
Email: jdykes@oag.state.md.us

THE STATE OF MICHIGAN
By its attorney,
BILL SCHUETTE
Attorney General

By: /s/ Deborah Harper
Deborah Harper
Assistant Attorney General
Michigan Department of Attorney General
Phone: (517) 241-6500
Fax: (517) 241-6515
Email: HarperD3@michigan.gov

THE STATE OF NEW JERSEY
By its attorney,
JOHN JAY HOFFMAN
Acting Attorney General

By: /s/ Joshua Lichtblau
Joshua Lichtblau
Assistant Attorney General
Medicaid Fraud Control Unit
New Jersey Division of Criminal Justice
Phone: (609) 984-7614
Fax: (609) 292-7410
Email: lichtblauj@njdcj.org

THE STATE OF NEW YORK
By its attorney,
ERIC T. SCHNEIDERMAN
Attorney General

By: /s/ Christopher Y. Miller

Christopher Y. Miller
Diana Elkind
Special Assistant Attorneys General
New York State Office of the Attorney General
Medicaid Fraud Control Unit
120 Broadway, 12th Floor
New York, New York 10271
Phone: (212) 417-5390/4171
Fax: (212) 417-4604
Email: Christopher.Miller@ag.ny.gov
Email: Diana.Elkind@ag.ny.gov

THE STATE OF OKLAHOMA
By its attorney,
SCOTT PRUITT
Attorney General

By: /s/ Niki S. Batt

Niki S. Batt
Christopher P. Robinson
Assistant Attorneys General
Medicaid Fraud Control Unit
Oklahoma Office of Attorney General
313 NE 21st Street
Oklahoma City, OK 73105
Phone (Batt): (405) 522-2956
Phone (Robinson): (405) 522-2968
Fax: (405) 522-4875
Email: Niki.Batt@oag.ok.gov
Email: Christopher.Robinson@oag.ok.gov

THE STATE OF WISCONSIN
By its attorney,
J.B. VAN HOLLEN
Attorney General

By: /s/ Katie M. Wilson

Katie M. Wilson
Wisconsin Department of Justice
Assistant Attorney General
Division of Legal Services
17 West Main Street
PO Box 7857
Madison, WI 563707-7857
Phone: (608) 261-8116
Fax: 608-261-7991
Email: wilsonkm@doj.state.wi.us